

# Exhibit 23

# PRICED OUT OF A LIFESAVING DRUG: GETTING ANSWERS ON THE RISING COST OF INSULIN

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## HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED SIXTEENTH CONGRESS FIRST SESSION APRIL 10, 2019 **Serial No. 116-25**



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**Testimony of Michael B. Mason**  
**Senior Vice President, Connected Care and Insulins at Eli Lilly and Company**

**Before the**

**United States House of Representatives**  
**Committee on Energy and Commerce**  
**Subcommittee on Oversight & Investigations**

Chair DeGette, Ranking Member Guthrie, and Members of the Subcommittee; Chairman Pallone, Ranking Member Walden, and other Distinguished Members: My name is Mike Mason, and I am the Senior Vice President for Connected Care and Insulins at Eli Lilly and Company (“Lilly”). Thank you for the opportunity to participate in today’s hearing. I would also like to thank the members of your staff who took the time to meet with us to discuss the important issue of affordable access to diabetes medications. I am pleased to be here today to continue our conversation.

Like many people who work at Lilly, I have a personal connection to the issues we will discuss today. Four of my immediate family members live with diabetes. I have seen them cope with the daily burdens of the disease, including finger pricks and insulin injections before each meal. I have seen the devastating complications of diabetes in their lives, and I know first-hand how they benefit from new, innovative treatments. Often our phone calls and visits turn to their diabetes. Over the years, these conversations centered on how they were managing their diabetes. But within the last 2-3 years, these conversations have changed. We now spend more time talking about how much they pay for insulin.

As a leader at Lilly, it’s difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don’t have affordable access for chronic medications.

Achieving affordable access to medications for everyone will require multiple groups to work together, including manufacturers, pharmacy benefit managers, health insurers, distributors, pharmacies, employers, and policymakers. But while long-term solutions are being discussed, Lilly knew we had to act to provide solutions today. Lilly has long provided support for individuals having trouble affording their insulin, including through savings cards and our support of the Lilly Cares Foundation. Over the past several years, however, we have recognized that there is an increased need to address affordability challenges and have been implementing a wide range of initiatives to make our insulins as affordable as possible for as many people as possible.

In 2017, Lilly began participating in savings programs that provide a 40% discount to those with private insurance. We also began the process of commercializing a lower-priced version of our most commonly prescribed insulin, Humalog U100, that will have a wholesale acquisition cost (WAC) or “list price” that is 50% lower than branded Humalog. Our goal is to make a lower-priced insulin alternative available within the limits of the current health care system. Earlier this year we received a response from federal regulators that allowed us to move forward, and we are now bringing this product, called Insulin Lispro, to the market.

We have also implemented other solutions. For example, we provide automatic discounts at the pharmacy counter that cap the cost of a prescription for Lilly insulins at \$95 for those in the deductible phase of high-deductible plans. This is a significant benefit for those in the deductible phase of high-deductible plans, who might otherwise be paying thousands of dollars for their insulin before their deductible is met. In addition to these automatic discounts at the pharmacy, we launched the Lilly Diabetes Solution Center, which connects individuals to a suite of affordability solutions. With these programs and others, we’ve built a safety net to try to

prevent anyone from falling through the cracks and having to pay retail price for their Lilly insulins.

Our solutions are working to reduce out-of-pocket costs. Today 95% of prescriptions for Humalog in the U.S. cost consumers less than \$95 at the pharmacy, 90% cost less than \$50, and 43% cost \$0.<sup>1</sup> As Insulin Lispro launches and is added to formularies and we continue to educate the diabetes and medical community about our Lilly Diabetes Solution Center, even more people will pay less for Humalog.

Although Lilly has taken steps to make insulin more affordable, we recognize that broader systemic change in our current healthcare system is needed. This will require action by all relevant stakeholders, but we are ready to play our role and we are confident that a solution is possible. We look forward to continuing our dialogue with the Subcommittee and other stakeholders about these important issues.

**I. Lilly's Investments in Treatments for People Living with Diabetes**

Eli Lilly was founded in Indiana in 1876 and remains a U.S. company. We employ over 16,000 people in the U.S. Our headquarters are in Indianapolis—as they have been for over a hundred years—and we also have a significant manufacturing and research and development presence in New Jersey, California, New York, and Massachusetts.

Lilly has been committed to helping people with diabetes for nearly a century. In 1923, Lilly introduced the world's first commercially-available insulin product, at a time when a diagnosis of diabetes was virtually a death sentence. While this was an incredible breakthrough that saved lives, the insulin was sourced from animals using what would by today's standards

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<sup>1</sup> Based on IQVIA data, FIA data (August 2018 – December 2018).

seem a crude process and one that raised supply and quality concerns. Over many years, advances were made to enhance the purity, concentration, and dosing regimen of that first insulin. As technology continued to evolve, in 1982, Lilly introduced human insulin, the world's first human health care product created using recombinant DNA technology.<sup>2</sup>

Since then, Lilly has spent billions of dollars in research and development to improve the lives of people with diabetes. In 1996, Lilly launched a new biotech insulin, Humalog, which mimics the body's own rapid insulin response. Humalog has made it easier for people with diabetes to manage their blood glucose and facilitated advancements in modern insulin pumps. In 2015, Lilly obtained approval for the first follow-on insulin biologic, Basaglar, which introduced significant competition in the long-acting insulin market as the lowest-priced basal analog available. This product currently has a list price that is 23% lower than the list price of the most commonly prescribed basal insulin, Lantus®. In 2018, Lilly announced its investment in a drug discovery partnership that we hope could move people with diabetes away from insulin altogether by developing cell therapies that would allow insulin-producing pancreatic beta cells to be delivered through implanted devices.<sup>3</sup> Lilly is also active in the space of digital health solutions and is developing a connected diabetes system consisting of devices that we hope will improve adherence, outcomes, and convenience. Before the discovery of insulin, a child diagnosed with Type 1 diabetes at age 10 typically died within 2.3 years of diagnosis. Insulin was literally life-saving: It expanded the life expectancy of the average person with Type 1

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<sup>2</sup> <https://www.lilly.com/milestones-of-lilly-caring-and-discovery>.

<sup>3</sup> *Lilly and Sigilon Therapeutics Announce Strategic Collaboration to Develop Encapsulated Cell Therapies for the Treatment of Type 1 Diabetes* (Apr. 4, 2018), <https://www.prnewswire.com/news-releases/lilly-and-sigilon-therapeutics-announce-strategic-collaboration-to-develop-encapsulated-cell-therapies-for-the-treatment-of-type-1-diabetes-300624199.html>; Alex Keown, *Eli Lilly Plunks Down \$63M Upfront in Deal With Startup Sigilon* (Apr. 4, 2018), <https://www.biospace.com/article/eli-lilly-plunks-down-63m-upfront-in-deal-with-startup-sigilon/>.

diabetes into the early 40s, and eventually to where it is today in the late 60s. But our work is not done. Our hope is that one day the life expectancy for a person diagnosed with diabetes will be no different than any other American.

Lilly is proud of our history of innovation in the treatment of diabetes, but improved medications and technologies will result in better outcomes only if people with diabetes have affordable access to them. Affordability is of critical importance to Lilly, and it's an area where we have invested time and resources to develop solutions.

## **II. The Current U.S. Healthcare System: Prices, Rebates, and Insurance Design**

The recognition that people increasingly face high out-of-pocket costs for their insulin caused all of us at Lilly to reflect on how we got here and what actions we could take to try to solve this problem in the short-term and in the long-term. The U.S. healthcare system has evolved over the last six to seven years. Historically, people with diabetes paid only a flat co-pay at the pharmacy, and insurance plans covered most medications. More recently, however, the market began moving to restrictive formularies,<sup>4</sup> which limit the number of medications covered on someone's health plan. In some classes like meal-time insulin, insurers started covering only a *single* brand of medication. To ensure that people's insurance plans would continue to cover their treatments, pharmaceutical companies, including Lilly, have had to pay larger discounts in the form of rebates. At the same time, mandatory discounts for federal programs were also increasing. With the cost to secure access increasing, pharmaceutical companies raised list prices<sup>5</sup> to remain viable, maintain access for patients using their

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<sup>4</sup> Drug formularies are ranked lists of drugs that insurers and PBMs use to determine whether certain medicines will be covered by insurance.

<sup>5</sup> Any discussion of drug pricing within the current system requires a clarification of terms because the "price" or "cost" of a medication may represent different concepts to different participants in the healthcare system. Manufacturers like Lilly typically set a medication's "list price," which is the amount that the manufacturer charges

medications, and ensure that they are able to continue to fund lifesaving research and development.

Because of the increasing rebates and fees that Lilly provides to purchasers and insurers (or their PBMs), and other fees and costs Lilly incurs, increases in list prices for Lilly insulins have not necessarily resulted in net price increases. For example, between 2014 and 2018, for our most broadly used Lilly insulin product, Humalog U100, the list price increased by 51.9%.<sup>6</sup> During that same time period, the amount of rebates Lilly paid increased at a greater rate, causing the average net amount that Lilly received—often referred to as the “net price”—to decline by 8.1%.<sup>7</sup> That translates into insurance plans on balance paying a lower net effective price for Humalog.

The chart below shows the average list price and net price for Humalog U100 from 2014 through 2018.<sup>8</sup>

to its wholesale distributor customers. The wholesalers then re-sell the medication to pharmacies at a price that those parties separately negotiate. The pharmacies, in turn, dispense the medication to patients and in most cases are paid a price that is individually negotiated by the patient's insurer or by a PBM retained by the insurer. Importantly, manufacturers typically provide rebates and/or fees to insurers or their PBMs, and to federal and state health programs, that reduce the cost of the medication to those entities. Manufacturers also pay other discounts and fees and incur costs related to co-pay assistance to patients and affordability programs. All of these payments reduce the amount that is ultimately realized by the manufacturer (which is sometimes referred to as a “net price”).

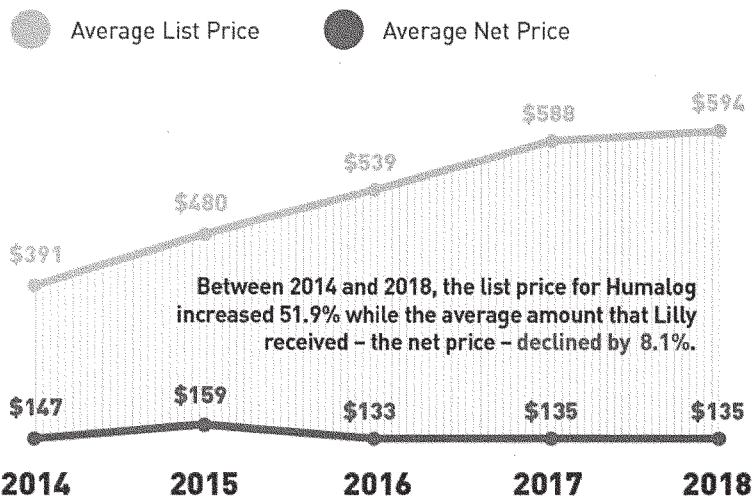
<sup>6</sup> Eli Lilly and Company 2018 Integrated Summary Report at 16, <https://investor.lilly.com/static-files/ae580ba4-5d84-4862-a5d2-99a1d784d7a8>. Humalog U100 is the most broadly used Lilly insulin product. The last list price increase for Humalog U100 was May 2017. The net price in the chart represents the average revenue Lilly realized per patient per month for Humalog U100 if taken as prescribed. Because of rebates and fees Lilly provides insurers and/or PBMs, increases in list prices do not always reflect increases in net prices.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

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**HUMALOG® (U100) AVERAGE LIST AND NET PRICE (USD)  
PER PATIENT PER MONTH, IF TAKEN AS PRESCRIBED\***



\*Average List and Net price per patient per month is calculated based on average prescribed utilization of Humalog U100, the most broadly used presentation of Humalog (Source: IQVIA LAAD Data 2014-2018). In 2018, per IQVIA reported data, if taken as prescribed, the average Diabetes patient using Humalog U100 would have consumed approximately 19 MLs of insulin per month; this equates to approximately 2 vials or 6.4 Kwikpens. The actual utilization per patient per month may differ significantly depending on multiple factors, including prescription amounts and adherence behaviors.

Overall, the system continues to work well for the majority of people who are prescribed a Lilly insulin. As noted above, the out-of-pocket cost for Humalog, Lilly's most commonly prescribed insulin, is less than \$50 a month for 90% of retail prescriptions, and less than \$100 for 95% of retail prescriptions.<sup>9</sup> Moreover, as discussed further below, individuals without

<sup>9</sup> Based on IQVIA data, FIA data (August 2018 – December 2018).

insurance or on Medicare Part D whose income is less than 400% of the federal poverty line can obtain Lilly insulins for free.

Additionally, under Medicaid, Lilly insulins are available at little or no cost to individuals or to the government.<sup>10</sup> Indeed, Humalog is essentially free to Medicaid programs, as Lilly pays a rebate of approximately 100%.<sup>11</sup> Public programs designed to assist the medically needy and financially vulnerable, including Medicaid, have expanded greatly in recent years. With enactment of the Affordable Care Act (“ACA”), the Medicaid population increased from 54.5 million in 2010 to 73.4 million in 2017.<sup>12</sup> Providing insulin to this population at little or no cost is a significant step towards ensuring affordable access for those in need.

But despite the fact that the current system works well for the majority of people prescribed Lilly insulin, we recognize that it does not work for everyone. Individuals’ specific out-of-pocket costs vary significantly depending on numerous factors, most notably the type and terms of their insurance coverage, which Lilly does not control. Depending on the terms of someone’s insurance, list price changes often have no effect on their out-of-pocket costs for insulin. But some people, including those enrolled in high-deductible health plans and Medicare Part D, may incur higher out-of-pocket costs for certain prescriptions because of their insurance design. Although Lilly pays a rebate for access on insurance plans, patients don’t always benefit from the rebates at the pharmacy.

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<sup>10</sup> Letter from Joe Kelley to Hon. Greg Walden *et al.* at 21 (Feb. 27, 2019).

<sup>11</sup> Letter from Joseph Kelley to Hon. Frank Pallone, Jr. and Hon. Diana DeGette at 3 (Feb. 13, 2019).

<sup>12</sup> Statista, Total Medicaid Enrollment from 1966 to 2017 (in millions), <https://www.statista.com/statistics/245347/total-medicaid-enrollment-since-1966>.

### III. Gaps in Affordable Access

Lilly has long provided support for people living with chronic conditions who face high out-of-pocket costs for their medications, but in recent years we have recognized an increasing need to address affordability challenges, as more people bear a greater share of their medications' costs. To that end, Lilly has focused on identifying the primary coverage gaps for people taking our insulins and has identified three groups of people most likely to be paying higher out-of-pocket amounts: (1) individuals in the deductible phase of private high deductible health plans; (2) individuals in the coverage gap phase (or "donut hole") of Medicare Part D; and (3) individuals without insurance. Each of these gaps is detailed below.

#### High Deductible Private Insurance

In recent years, employers focused on providing employees health insurance plans with low premiums and increasingly selected high deductible health plans to achieve that. These plans require members to pay thousands of dollars before insurance coverage starts. In about half of these plans, employers give special treatment to medication for chronic diseases, such as exempting those medicines from deductible requirements through the use of preventive drug lists. In the other half, employers choose a plan design that utilizes rebates paid by pharmaceutical companies on drugs like insulin to buy down premiums for the general population. The result is that people who take insulin or other medications for chronic conditions pay full retail prices at the pharmacy during the deductible phase of coverage and do not directly benefit from rebates paid in connection with those medicines. This places a great burden on people with diabetes and others who rely on medications to treat chronic conditions.

Medicare Part D Coverage Gap

Once a person covered by Medicare Part D has spent a certain amount on covered prescription drugs, a coverage gap known as the “donut hole” begins. While in that phase, the person will pay up to 25% of the plan’s cost for brand-name drugs. Our review of data indicates that since enacting our current safety net of solutions, almost 90% of the people exposed to a prescription cost above \$100 for Humalog at a retail pharmacy were enrolled in Medicare Part D. In most cases, federal regulations prohibit Lilly from subsidizing the cost of insulin for people on Medicare during the coverage gap.

No Insurance

The third primary group of people that Lilly has identified as lacking access to affordable insulin are those without any insurance coverage, who pay retail price at the pharmacy throughout the year. Lilly estimates that each month there are approximately 1,600 prescriptions for Humalog filled at a retail pharmacy by likely uninsured individuals or individuals in a period of transition between insurance coverage who pay near list price for their prescription.

**IV. Lilly’s Solutions**

Recognizing that individuals exposed to high prescription drug costs have a real and pressing need for immediate solutions, particularly those who rely on medications to treat life-threatening, chronic conditions like diabetes, Lilly has instituted multiple programs designed to reach each of the segments of people who need assistance affording their insulin.

These solutions are currently helping more than 20,000 additional people each month more easily afford their insulin. We want people to use our solutions, and our intent is to make these solutions as easy to access as possible. For example, if you are uninsured or have private

insurance you can gain immediate access to savings offers with no paperwork or applications to complete. If you or a loved one is having trouble paying for our insulin, please call our Lilly Diabetes Solution Center at 833-808-1234. Lilly's solutions are discussed further below.

#### Automatic Discounts

Lilly currently offers savings directly to people in the high-deductible phase of their insurance plans by capping their prescription cost at \$95 at the pharmacy. When a person in a high-deductible insurance plan fills a prescription for a Lilly insulin, the individual generally will pay no more than \$95 out of pocket at the pharmacy, and Lilly will pay the remainder of the cost.<sup>13</sup> The discount is automatically applied at the point of sale, and therefore has an immediate impact on the cost paid by the insured person. This takes place behind the scenes when the insurance claim is processed and does not require the individual to enroll in any programs or request that the savings offer be applied. In fact, individuals may not even be aware of these "buy-downs" or may be surprised by them.

These buy-downs are in addition to the rebates that Lilly is already paying. Indeed, when Lilly pays the cost of a person's prescription during the deductible phase and also continues to pay the full contractual rebate, it loses money on each prescription. This is not a sustainable long-term solution, but it is one that Lilly felt was necessary to ensure that individuals had access to affordable insulin while we work towards broader systemic changes.

These automatic discounts are not available to all people, however. Federal regulations prohibit us from subsidizing prescriptions for people insured through government programs such

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<sup>13</sup> Significantly, the portion that Lilly pays is counted towards the patient's deductible.

as Medicare Part D. This program also cannot be used by individuals without insurance because there is no insurance claim to process, triggering the savings offer.

#### Lilly's Insulin Lispro

As discussed above, we recently announced the introduction of a lower-priced version of Humalog. We sought to bring a lower-priced version of our product to the market because we recognized that other solutions, though important, still left some people vulnerable to high out-of-pocket amounts for insulin. We expect the introduction of Lilly's Insulin Lispro to particularly benefit individuals enrolled in Medicare Part D who are on the coverage gap. Because of legal restrictions outside of our control, these individuals do not have access to as many of our other solutions as people covered by private insurance plans. By introducing this second version, Lilly can provide a lower-priced insulin quickly without disrupting access to branded Humalog, on which hundreds of thousands of people currently depend.

It is important to note that our introduction of Insulin Lispro will not prevent any other companies from manufacturing a generic version of Humalog. None of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product.

#### Other Discount Programs

Since 2017, Lilly has participated in Blink Health ([www.blinkhealth.com](http://www.blinkhealth.com)) and Inside Rx ([www.INSIDERx.com](http://www.INSIDERx.com)), savings programs that offer savings of up to 40% off the list price of Lilly's most commonly prescribed insulins. These programs are available to people through smart phone applications and offer savings at the point of sale. Our participation in these

programs was an initial step to provide discounts to people on Lilly insulins who had private insurance or were uninsured.

#### Donations of Free Insulin

For many years, Lilly has provided free insulin products to a variety of organizations and programs. We broadened the scope of that support from emergency relief organizations to include donations to relief networks that supply insulin to nearly 150 free clinics. These clinics provide not only free insulin, but also access to medical care and other free medications and supplies.

Since January 1, 2014, Lilly has provided over 5 million free pens/vials of Humalog, Humulin, and Basaglar to these organizations and programs in the U.S. Program qualification requirements vary depending on the nature of the program and as determined by the organization, but in all instances, the insulin provided is free to qualifying individuals.

#### Lilly Cares

Lilly also supports and donates insulin to Lilly Cares, a separate charitable organization.<sup>14</sup> Lilly Cares provides free insulin to patients who do not have insurance or have Medicare Part D and have a household annual adjusted gross income of up to 400% of the federal poverty level.

#### Lilly Diabetes Solution Center

Recognizing that some solutions described above will not help people unless they know about them, Lilly launched the Lilly Diabetes Solution Center (“LDSC”) in August 2018. The Solution Center is a patient-focused helpline staffed by medical professionals, which connects

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<sup>14</sup> <https://www.lillycares.com/resources.aspx>.

people living with diabetes to any of Lilly's various resources and solutions based on their individual needs. These solutions include savings cards (requiring no paperwork and no application), an immediate supply of insulin, or information about one of the clinics that can offer free insulin that Lilly has donated. The LDSC also can connect patients to Lilly Cares. Lilly has publicized the LDSC through press releases, social media channels, and advertising campaigns—including direct-to-consumer print ads—that directly target people with diabetes, the general public, and specific communities of color with a higher risk of diabetes.

These solutions help ensure that insulin is affordable for people who fall within the coverage gaps described above. But some people might ask—why doesn't Lilly just drop the list price of its insulin products? This is an important and fair question. The answer is that lowering list prices is too disruptive under the current health care model. Distributors, PBMs, insurance companies, long-term care facilities, and pharmacies have all entered into contracts that are based on a rebate model tied to current WAC or list prices. No pharmaceutical manufacturer has lowered list price for a significant medication because it is too disruptive to the system and thus to people who rely on that medication. Introducing a new, lower list price second version of a medication is the only practical approach under the current health care model. In the face of these complex dynamics, systemic change is needed. In the meantime, we have taken action within the constraints of the current system to lower insulin prices, for example by introducing a half-price version of Humalog.

#### **IV. Towards a New Approach**

While Lilly has worked hard to introduce the many solutions it has in place to make insulin affordable for people with diabetes today, we recognize that we need more than a series of patchwork fixes, and that long-term change will require the participation of all industry

stakeholders. We appreciate the Subcommittee's attention to these important issues, and we look forward to continued dialogue about potential solutions.

One proposal that Lilly believes is worthy of consideration is adding insulin to preventive medications lists, which would lower out-of-pocket costs such as by exempting insulin from deductibles (sometimes called "first dollar coverage"). Because of how the private health care system works today and the complexity of high deductible health plans, some people have full coverage for treatments to manage their chronic conditions while others must meet out of pocket and deductible requirements for the same treatments. Making people with chronic diseases like diabetes pay high prices for their medications does not make sense as a matter of public policy. While billions of dollars are spent in the United States each year on medical expenses directly related to diabetes, only 6% of that is spent on insulin.<sup>15</sup> The vast majority is spent to treat the serious and costly complications of diabetes. When people with diabetes take their medications, they live healthier lives, reducing overall health care costs. As a result, insurance design that makes insulin and other medications for chronic conditions available at low out-of-pocket costs is a matter of sound public policy.

A nationwide systemic preventive drug list that assesses the holistic nature of treatment and takes into account the overall savings afforded by access to preventive treatment would address this disparity in affordability, while also reducing overall costs to the system. We also look forward to the re-introduction of the Chronic Disease Management Act in this Congress which will provide legal certainty to health plans that want to exempt chronic medications from deductible requirements.

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<sup>15</sup> American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017* at 8 (Mar. 22, 2018), <http://care.diabetesjournals.org/content/diacare/early/2018/03/20/dci18-0007.full.pdf>.

Lilly also supports the policy objective of reducing the out-of-pocket burden as advanced by HHS' recently proposed rule.<sup>16</sup> We believe the proposal has the potential to lower peoples' out-of-pocket costs at the pharmacy counter by enabling manufacturers' discounts to flow directly to individuals. But in order to effectively address this issue, the proposal must be extended to private insurance, not just Medicare Part D.

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As I explained above, for me, ensuring affordable access to diabetes medication is personal. Like all of us at Lilly, I recognize the impact of higher out-of-pocket costs on individuals struggling to afford their insulin. We are committed to doing our part to address this issue in a meaningful way.

Thank you for the opportunity to be here. I look forward to your questions.

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<sup>16</sup> See HHS, Proposed Rule, *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2340 (Feb. 6, 2019).

Ms. DEGETTE. Thank you.

Mr. Langa, you are recognized for 5 minutes.

**STATEMENT OF DOUGLAS J. LANGA**

Mr. LANGA. Thank you, Chair DeGette, Ranking Member Guthrie, and members of the subcommittee. My name is Doug Langa. I am the Executive Vice President, North America, and I am the President of Novo Nordisk Incorporated.

For over 90 years, Novo Nordisk has been dedicated to improving the lives of people with diabetes. We care deeply about the people who need our medicines and we're troubled knowing that for some our products are unaffordable. For a company committed to helping people with diabetes, patients rationing insulin is just simply unacceptable. Even one patient rationing insulin is one too many. We need to do more. We all need to do more. This is why I appreciate the opportunity to take part in a dialogue here today.

On the issue of affordability, we all hear a lot about list price, and I will tell you that at Novo Nordisk we are accountable for the list prices of our medicines. We also know that list price matters to many, particularly those in a high-deductible health plan and those that are uninsured. Why can't we just lower the list price and be done? In the current system, lowering list price won't bring meaningful relief to all patients, and it may jeopardize access to the majority of patients who have insurance and are able to get our medicines through affordable copays. That's because list price is only part of the story. Once we set the list price, the current system demands that we negotiate with PBMs and insurance plans to secure a place on their formularies. Formulary access is critical because it allows many patients to get our medicines through copays at reasonable costs. The demand for rebates has increased each and every year. In 2018, rebates, discounts, and other fees accounted for 68 cents of every dollar of Novo Nordisk gross sales in the U.S. As a result, net prices of our insulin products have declined year over year since 2015. Despite the investment that we make in rebates, some patients including those with insurance end up paying list price or close to it at the pharmacy counter. As a manufacturer, Novo Nordisk has no control over what insured patients pay at the pharmacy counter. This is dictated by benefit design.

In the last few years, we've seen more patients with benefit designs that require them to pay high out-of-pocket costs, so despite these ever-increasing rebates that we pay to get on formularies, patients don't get the full benefit of those rebates at the pharmacy counter. This needs to change. It's time for people with diabetes to benefit directly from the rebates that we pay. I take the mission of this company to help people with diabetes very seriously and personally. I lost my own father-in-law to this disease, so I do know firsthand what it does and how it affects patients and their families.

When the healthcare market began to shift toward high-deductible health plans and we saw that more people were struggling to afford their medications, we took action. Back in 2016, we pledged to limit list price increases to single-digit percentages annually. We were one of the first companies to make that commitment and we

have honored it ever since. Our pricing pledge complemented other programs that we've had in place for years with the goal of reducing patients' out-of-pocket costs.

Through our nearly two decades old partnership with Walmart, Novo Nordisk's high-quality human insulin is available at Walmart pharmacies for less than \$25 a vial. In 2017, we partnered with CVS Health and Express Scripts to expand the \$25 human insulin offerings to tens of thousands of pharmacies nationwide. Our human insulin is an FDA-approved, safe and effective treatment for both type 1 and type 2 diabetes and it's used by about 775,000 patients today.

Since 2003, we have also provided free insulin to eligible individuals through our Patient Assistance Program. Nearly 50,000 Americans received free insulin through the effort in 2018 alone. Today, a family of four making up to \$103,000 a year could qualify for a Patient Assistance Program. We also offer copay assistance on a wide variety of our insulin medicines which last year helped hundreds of thousands of patients lower what they pay at the pharmacy counter.

Although these valuable programs help many people today, we can't stop there. Patients are telling us that we need to do more, and we hear them. The challenge is that the current system is broken. Bringing relief to patients is going to require bigger, more comprehensive solutions built on cooperation between all stakeholders in the insulin supply chain. We want to be a part of those solutions, and we look forward to working with all stakeholders to ensure that this lifesaving medicine remains available to everyone who needs it.

Thank you and I do look forward to answering the questions today.

[The prepared statement of Mr. Langa follows:]

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TESTIMONY OF DOUGLAS J. LANGA  
NOVO NORDISK INC.  
BEFORE THE U.S. HOUSE OF REPRESENTATIVES  
COMMITTEE ON ENERGY AND COMMERCE  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS  
APRIL 10, 2019

*Introduction*

Chairwoman DeGette, Ranking Member Guthrie, and Members of the Committee, on behalf of the over 42,000 employees of Novo Nordisk, including nearly 6,000 in the United States, I appreciate the opportunity to be here for today's hearing. My name is Doug Langa, and I am the Executive Vice President, North America Operations, and President of Novo Nordisk Inc. I joined the company in 2011, after working in the pharmaceutical and device industries in a number of roles for more than 25 years, including in marketing, market access, sales, and accounts management.

At Novo Nordisk, we are dedicated to improving the lives of patients living with diabetes and supporting efforts to prevent its life-threatening complications. As an industry leader in developing innovative treatments for diabetes, we are deeply concerned about the factors that limit access to our medicines—including affordability. It is our ambition that everyone who could benefit from our medicines can access them, at costs that they can afford.

My testimony today will offer our company's perspective on the pressures that exist in the U.S. healthcare system around the pricing of insulin medications, including how changes in benefit designs and the increasing commonality of high-deductible health plans have contributed to rising out-of-pocket costs for prescription medicines. My testimony will also address the innovation that has occurred in insulin and diabetes care and management. This is an important issue, as some have inaccurately suggested that insulin therapy has not changed since it came into use approximately 100 years ago. The truth is that the insulin medicines we sell today, including human insulin, are not the same therapies that were used nearly a century ago. Innovations in insulin and diabetes care over the years have dramatically improved the way patients manage their disease. And we are not slowing down; we have new treatments in the pipeline that will continue to meaningfully improve patients' lives.

Further, I will discuss Novo Nordisk's commitment to addressing affordability. Novo Nordisk provides a number of programs to help patients who cannot afford their medications—some of these programs have been in place for nearly two decades. As I will describe in further detail, Novo Nordisk offers a diabetes Patient Assistance Program ("PAP") and co-pay assistance programs; and partners with Walmart, CVS Health, and ESI to offer high quality Novo Nordisk human insulin for approximately \$25 a vial. While these programs are important options when

patients do not have adequate insurance coverage, they are not a substitute for the much needed reform to the drug supply chain.

We can—and must—do our part to bring relief for patients who cannot afford the out-of-pocket costs of their medications. But we cannot solve the affordability problem alone. The U.S. healthcare system is complex, and many entities play a part in determining what patients pay for their prescriptions. A solution that will bring meaningful relief for patients must address the roles of all participants in the drug supply chain.

Pharmaceutical companies set the Wholesale Acquisition Cost (known as “WAC,” and also commonly referred to as the “list” price) which is the price we charge to wholesalers and distributors who purchase medicines from our company. How pharmaceutical companies like Novo Nordisk set WAC, or list, prices and the relationship these prices bear on the ultimate price patients pay at the pharmacy counter should be examined. But WAC price is only part of the story, and any effort to understand and solve the problems inherent in the supply chain for prescription medicines must explore the rebates, discounts, and fees paid to pharmacy benefit managers (“PBMs”), insurance plans, distributors, and other entities in the supply chain. After our medicines leave our facilities and enter the supply chain, we have limited visibility into how the actions of downstream entities ultimately impact the price that patients pay for medicines at the pharmacy counter. We look forward to working with this Committee, and other stakeholders in the complex U.S. healthcare system, to develop solutions that will help patients affordably access the medications they rely on.

As described at the close of this testimony, I will address some of the proposed solutions that Novo Nordisk believes could bring meaningful change for patients. Novo Nordisk is committed to doing its part and to helping find solutions to the very real affordability challenges that patients are experiencing.

#### *About Novo Nordisk*

For more than 90 years, Novo Nordisk has been uniquely focused on the development of pharmaceutical products and devices to help people with diabetes. The company began when a husband and wife from Copenhagen, August and Marie Krogh, a professor and physician respectively, visited the United States in 1922 and learned that people with diabetes were being treated with insulin. Mrs. Krogh was a physician who herself had type 2 diabetes, but she also treated patients with type 1 diabetes in her practice. After meeting with the two Canadian researchers who discovered insulin, Mr. and Mrs. Krogh brought that innovative therapy back to Denmark.

While our company has grown rapidly since its founding, and we have broadened our work to include medications to treat obesity, hemophilia, and hormone imbalances, our principal mission since day one has been improving the lives of people with diabetes. Today, over 29 million patients use our diabetes products, and our medications are available in more than 170 countries. In the United States, we offer a variety of diabetes medicines, including short- and long-acting insulins and Glucagon-like peptide-1 receptor agonist (“GLP-1”) products for diabetes and obesity. We also offer innovative delivery methods, including injection pens that make dosing and administration of medicines more convenient and less painful for patients.

Although we are proud of the innovative therapies we have been able to bring to patients, we recognize that prevention is more effective than even the best treatment. For that reason, Novo Nordisk has created initiatives dedicated to the prevention and early detection of type 2 diabetes.

The innovative medicines and delivery systems we produce are the result of significant and ongoing investment in research and development. But we know that these investments will not help patients if they cannot afford the out-of-pocket costs for our medicines. Like you, I am deeply troubled by reports of patients rationing insulin because they cannot afford it. As a company whose legacy is rooted in the treatment of this serious disease, the people of Novo Nordisk believe that this is unacceptable. Even one patient rationing insulin is one too many.

#### *The U.S. Healthcare System and Insulin Pricing*

As an innovator and manufacturer of prescription medicines, Novo Nordisk sets the WAC price for the medicines it sells. Although many other participants in the healthcare supply chain impact what patients ultimately pay at the pharmacy counter, there is no doubt that the WAC price is a significant component, particularly for those patients with high-deductible health plans, those who have co-insurance, and those who are uninsured and not covered by any government drug benefit programs.

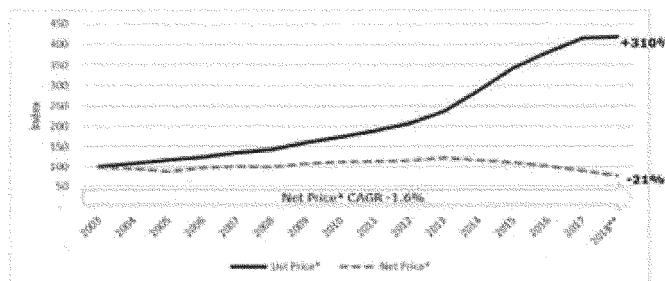
It is important to recognize, however, that WAC price is not set in a vacuum. Rather, WAC price is set against the backdrop of the competitive environment in which we operate. After Novo Nordisk sets the WAC price, we negotiate discounts, rebates, and other price concessions with supply-side entities, like PBMs, who act on behalf of employers and health insurers and determine whether our medications will be covered on their formularies. Because of consolidations that have occurred over the past several years, the PBMs testifying here today now control access to medications for over 80 percent of the covered U.S. population, or roughly 220 million people. With such a substantial market share, these companies are able to exert considerable leverage in negotiations. If they do not extract the rebate concessions they demand (and we recognize that PBMs are under pressure from employers and health plans to deliver certain dollar amounts in savings), they can and do exclude products from formularies, essentially making them unavailable to patients who rely on them every day. The pressure to provide higher rebates is constant and escalating, and rebate percentages have increased year-over-year for the last several years.

Recently, pharmaceutical companies have come under pressure to explain the increasing out-of-pocket costs for certain medicines, including insulin. While increased competition in a marketplace would usually lead to lower prices, our current healthcare system is built on misaligned incentives that have led to rising costs in medicines. Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others.

Exclusion from a major formulary would have significant consequences for patients and for our company. If our medicines were not covered on formulary, patients whose diabetes is well-controlled by a Novo Nordisk product would be forced to either switch to another product, which might not work as well for them, or pay much more to stay on their physician-prescribed Novo Nordisk medicine. This is not a hypothetical risk: just last week, the Committee heard from Gail deVore, who testified that she cannot afford Fiasp<sup>®</sup> because it is not on her formulary, and she therefore mixes it with NovoLog<sup>®</sup> against her doctor's orders. For the company, exclusion from a major formulary typically results in a significant financial loss (as well as loss of market share), which would compromise Novo Nordisk's ability to continue to innovate with the goal of defeating diabetes.

For these reasons, we are acutely focused on the rebates our payers, including PBMs, will demand when we set WAC prices. Last year, across all products and channels, we paid an average of 68 cents for every dollar of sales to PBMs and other payers and supply-side entities in the form of rebates and other discounts and fees—nearly \$17.8 billion. These rebates, discounts, and other price concessions are the single largest investment Novo Nordisk makes in ensuring its products are broadly available to patients. And the percentage we pay has been increasing each year—it is up from 64 percent in 2017, 59 percent in 2016, 56 percent in 2015, and 48 percent in 2014. Further, because of the portion of our gross sales consumed by rebates and other discounts, net prices for our medicines, including our insulins, have declined year-over-year for every year from 2015 through 2018, and experienced double-digit declines in 2017 and 2018. By way of example, the following graph shows WAC and net prices for NovoLog<sup>®</sup>Flexpen<sup>®</sup> dating back to 2003.

### NovoLog<sup>®</sup> FlexPen



\*Adjusted for inflation  
 \*\*2018 reflects December YTD  
 \*\*\* Y axis represents Annual List & Net Price Indices, adjusted for CPI-U  
 CAGR = compound annual growth rate



As this graph shows, WAC price increases (factoring in the negotiations and concessions described above) have translated year-over-year to a 1.6% overall decline in NovoLog®FlexPen® net price when adjusted for inflation.

In spite of its complexities, this system of WAC prices and rebates works for many patients who have health insurance and who are charged reasonable co-pays for their prescriptions. But it does not work for everyone: many patients do not see the full benefit of the discounts we provide to PBMs to secure formulary access, and some see little to no benefit at all. In particular, uninsured patients and patients covered by high-deductible health plans pay close to the full WAC price for our medicines. Others, such as those with co-insurance or Medicare Part D patients in the coverage gap, may also pay a substantial portion of the WAC price. This is true even where Novo Nordisk has already paid a substantial rebate to the PBM to secure formulary access for the particular medication.

Unfortunately, as a pharmaceutical company, we do not have the ability to control what an individual insured patient pays for his or her prescriptions; that is a function of the individual's health plan benefit design. Similarly, we do not have control over whether the rebates we pay to ensure formulary access actually result in lower out-of-pocket costs for patients; that is the decision of the PBM, which determines how to apply the rebate. But we do know that more patients are facing an affordability challenge. Although there have always been some patients without insurance or who pay an above-average portion of WAC price for other reasons (and Novo Nordisk has attempted to relieve the burden on those patients through various affordability programs, described below), the number of patients struggling to afford their medicines has grown in recent years. This is due, in part, to the increasing prevalence of benefit designs that require patients to shoulder large out-of-pocket costs, such as high-deductible health plans. The number of individuals covered by this type of plan has increased over the last ten years and, according to the Centers for Disease Control and Prevention, high-deductible health plans now represent approximately 43 percent of private insurance plans in the United States. For these patients, the price they pay at the pharmacy counter simply does not reflect the significant rebates Novo Nordisk provides to the PBMs managing their pharmacy benefits.

My intent in highlighting the problems inherent in the complex U.S. healthcare system is to underscore that fixing the rising out-of-pocket costs of prescription drugs will require the commitment of all stakeholders in the supply chain. We at Novo Nordisk are committed to doing our part. We recognize the impact that changes in the healthcare market, especially the growth of high-deductible health plans, have had on patients. As we became aware that more patients were struggling to afford their medicines, we took steps to try to address the problem, including our commitment in 2016 to limit WAC price increases to single digit percentages annually. We have honored that pledge since we made it. We have also expanded our affordability programs, which I describe in greater detail below. But we know that we can do more, and we will do more. Novo Nordisk looks forward to being part of the solution that helps patients obtain access to affordable medicines.

#### *Innovation in Diabetes Treatment and Care*

Over the last five years, Novo Nordisk has invested over \$10 billion in research and development, much of which is aimed at finding new therapies that improve diabetes patients'

ability to manage and live with this chronic disease. In fact, Novo Nordisk is the largest private funder of diabetes research and development in the world. Novo Nordisk has also formed research collaborations to further innovation in diabetes, including one with the Massachusetts Institute of Technology to develop a capsule device that contains compressed insulin, which is injected into the patient after the capsule reaches the stomach. This capsule would potentially replace insulin injections through pens or syringes, making it easier for patients to receive their medication. We are also conducting research into stem cell therapies to treat diabetes in collaboration with the University of California, San Francisco, as well as other chronic diseases. In 2016, we began a \$2 billion investment in a new production facility in Clayton, North Carolina, which, once operational in 2020, will be the only facility outside Denmark where we manufacture active pharmaceutical ingredients for diabetes medications. To our knowledge, this project is the largest active pharmaceutical manufacturing construction project in the United States. These are just some of the innovative and cutting-edge research and development and manufacturing projects underway at Novo Nordisk.

These efforts build on the work we have already done throughout Novo Nordisk's history to continuously improve our insulins and other medicines in a way that offers meaningful change to patients who live with this disease each day. Recently, some have suggested that the insulin now on the market is essentially the same product as the insulin first produced almost 100 years ago. That is simply not the case. Early diabetes treatments used bovine and porcine insulins. Novo Nordisk was the first to convert porcine insulin into human insulin in the 1980s using recombinant DNA technology. Human insulin revolutionized the treatment of diabetes because it could be produced in a purer form and reduced the occurrence of allergic reactions. Human insulin is an FDA-approved, high-quality treatment and remains safe and effective for managing both type 1 and type 2 diabetes. In fact, human insulin was used in the Diabetes Complications and Control Trial in the 1990s that set new standards of care in diabetes. Human insulin is part of the standard of medical care in the United States and throughout the world. Today, approximately 775,000 people in the United States use our human insulins. In 2018, those medicines constituted 21 percent of our insulins sold in this country and 44 percent sold worldwide.

The development of analog insulins in 2000 represented another significant change in diabetes therapies. Our analog insulin, which we sell under the name NovoLog<sup>®</sup>, is a modified form of human insulin in which the amino acid structure of the insulin molecule has been altered at specific sites to change the onset and duration. For patients, this provides better control of mealtime blood glucose levels by more closely matching the body's natural insulin action. In doing so, the medication allows for a more flexible lifestyle, as injections can be taken immediately before, or even just after, meals. This flexibility offers a meaningful improvement in quality of life for patients because it means that they do not have to take insulin at the same time every day.

Five years later, we launched Levemir<sup>®</sup>, a long-acting insulin that has shown improved glucose control benefits by providing blood sugar control for up to 24 hours and a reduction of hypoglycemia risk. In addition, Levemir<sup>®</sup> is considered to be weight neutral, meaning it is not typically associated with the weight gain patients often experience with insulin treatment.

In 2015, we introduced Tresiba<sup>®</sup>, a long-acting basal insulin, offering once daily dosing at any time of day for both type 1 and type 2 diabetes patients. This medication's unique mechanism of action allows for improved blood sugar control with a lower risk for nighttime hypoglycemia as compared to other basal insulins. In addition to its standard concentration, Tresiba<sup>®</sup> is available in a more concentrated formula for those patients who require higher doses of insulin, allowing them to take a single dose per day with a pen device. Most recently, in 2017, we introduced Fiasp<sup>®</sup>, a new short-acting insulin that offers quicker onset. These two recent advances, Tresiba<sup>®</sup> and Fiasp<sup>®</sup>, have allowed people who are insulin-dependent to safely and effectively control their diabetes around mealtime, when blood sugar rises quickly after eating, as well as overnight. For patients, better nighttime control may mean the difference between getting a good night's sleep and sleep interruptions caused by diabetes.

We have also created new, more accurate and convenient delivery systems that allow patients to take their insulin through pen injection devices rather than with a traditional vial and syringe.

These developments in diabetes care and treatment demonstrate Novo Nordisk's commitment to improving the lives of its patients through new medications and delivery systems. We will continue to innovate to address the needs of patients and to meet our goal of defeating diabetes.

*Novo Nordisk's Commitment to Patients and Affordability*

For many years, Novo Nordisk has invested in programs to help patients afford their medicines. Like our investments in research and innovation, we view these investments as part of our overall commitment to improving the lives of patients living with diabetes. Although these programs are not intended to take the place of adequate insurance coverage, they are important options that are aimed at ensuring all patients can successfully and affordably manage their diabetes.

Novo Nordisk has offered a Patient Assistance Program since 2003. The PAP provides free medicines, including all Novo Nordisk insulin medications, to eligible patients who do not have insurance; Medicare patients who incur high costs while in the Part D coverage gap or who do not have Part D coverage and have been denied the Extra-Help/Low-Income subsidy; and patients who are Medicaid eligible but have been denied Medicaid.<sup>1</sup> With a maximum income requirement of 400 percent of the federal poverty limit, 59 percent of American households could qualify for free Novo Nordisk medicines under our PAP.<sup>2</sup> Thus, a family of four with income up to \$103,000 may receive free medications through our PAP. For individuals, the income limit for participation is \$49,960. Typically, we are able to ship medicines to patients who qualify for our diabetes PAP within seven to ten days of the patient submitting a complete

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<sup>1</sup> Information about the PAP and its eligibility criteria can be found on the Novo Nordisk website. In addition, at [www.novocare.com](http://www.novocare.com), patients can get help on how to access our company's assistance programs and receive guidance about applying for these programs.

<sup>2</sup> See Kaiser Family Foundation, "Distribution of the Total Population by Federal Poverty Level (above and below 400% FPL)," at <https://www.kff.org/other/state-indicator/population-up-to-400-fpl/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

and accurate application. In 2018, nearly 50,000 Americans received free insulin from Novo Nordisk through this program.

In addition to the PAP, Novo Nordisk offers coupons or co-pay assistance to help patients by decreasing what they pay at the pharmacy counter. We offer this assistance on a variety of our medicines, including NovoLog<sup>®</sup>, Tresiba<sup>®</sup>, Levemir<sup>®</sup>, and Fiasp<sup>®</sup>. In 2018, Novo Nordisk provided more than \$200 million in assistance to patients through coupons and co-pay cards.

Through partnerships with Walmart, CVS Health, and ESI, Novo Nordisk human insulin is available at approximately \$25 a vial to any cash-paying patient, regardless of income and insurance coverage status. Through a longstanding partnership with Walmart (which began in 2000), safe and effective Novo Nordisk-manufactured human insulin is available at Walmart stores for \$25 per vial. In 2017, we partnered with CVS Health and ESI to expand the \$25 human insulin offering to tens of thousands of pharmacies nationwide. Last year, we also started to provide human insulin in a convenient pen injection device through Walmart. Through the CVS Health and ESI programs, commercially eligible patients can purchase this same Novo Nordisk insulin for around \$25 at 68,000 pharmacies in the CVS Health retail network and 40,000 ESI participating pharmacies. In total, through these partnerships, Novo Nordisk estimates that it is currently providing high quality, affordable Novo Nordisk-manufactured human insulin to over 500,000 people. While newer analog insulins offer significant improvements in terms of *how* they are absorbed into the body, human and analog insulins work exactly the same way in lowering blood glucose once in the bloodstream. In fact, the standards of care set by the American Diabetes Association guidelines do not recommend one type of insulin over another. It is my sincere hope that patients who are struggling to afford their insulin and who might be rationing will consider this affordable and safe option. Again, one patient rationing insulin is one too many.

Novo Nordisk has adjusted these programs over the years to address our patients' needs for affordable medications and to address the gaps inherent in the healthcare system. We will continue to monitor the effectiveness of these assistance programs, including enhancing outreach to patients and physicians to raise awareness of the programs we offer, so that all who need assistance may find a program that fits their needs. In addition, we will continue to explore additional steps to provide relief to patients who need it. However, as I have described, these are not comprehensive solutions, and more is needed to address a complex system in need of reform.

#### ***Policy Proposals***

In addition to the many ways Novo Nordisk demonstrates its commitment to people with diabetes, Novo Nordisk supports policy changes and legislation that, when implemented properly, benefit patients and address high out-of-pocket pharmacy costs.

One policy change that could help address affordability, particularly for patients with chronic diseases like diabetes, is the Chronic Disease Management Act ("CDMA"). Although this bill has not been introduced in the House of Representatives in this Congress, Novo Nordisk has consistently supported this bill in previous Congresses. The CDMA would require that the IRS preventive drug list include medicines that prevent chronic disease progression or

complications, like insulin.<sup>3</sup> Under current law, patients in a high-deductible health plan with a health savings account (“HSA”) must pay 100 percent of their treatment costs for chronic diseases unless deemed “preventive;” the definition of “preventive,” however, is narrow and only includes treatments that would prevent a disease in the first place. The CDMA would modify current law to give these plans the flexibility to cover services and medicines used to treat chronic diseases such as diabetes before meeting the plan deductible. As noted previously in this testimony, high-deductible health plans represent a growing percentage of plans offered today, with 20.2 million Americans enrolled in these plans in 2016.<sup>4</sup> Diabetes patients in high-deductible health plans with an HSA are particularly vulnerable to high out-of-pocket costs because their health plans are not responsible for providing any coverage for insulin until these patients spend through their respective deductibles. This can create significant financial hardships. As we have all seen, insulin rationing due to affordability can cause tragic and senseless deaths, as well as medical emergencies, which drive avoidable and expensive hospitalization costs. Novo Nordisk urges Congress to pass legislation to change the IRS definition of “preventive” to include insulin so that diabetes patients in high-deductible health plans with HSAs can gain first dollar coverage for insulin.

Novo Nordisk also fully supports the policies underlying the OIG’s proposed rebate rule.<sup>5</sup> The proposed rule, if appropriately implemented, will address some of the very challenges described earlier in this statement by moving Medicare Part D away from a system that provides rebates to entities such as PBMs and toward providing upfront pharmacy discounts to patients at the point of sale. Importantly, the proposed rule could lower patients’ out-of-pocket pharmacy costs for millions of Part D beneficiaries by realigning market incentives so that discounts are directed to those patients who need prescription drugs. While Novo Nordisk supports the proposed rule and its implementation in both Medicare Part D and the commercial market, we urge a cautious approach before making a full transition into the commercial market. Novo Nordisk believes that the wholesale conversion of both markets simultaneously could be challenging in the marketplace and disrupt patient access to medications.

Additionally, Novo Nordisk encourages adoption of policies that support diabetes prevention measures. Novo Nordisk has worked to improve access to diabetes prevention interventions by supporting increased funding for the National Diabetes Prevention Program (“DPP”). The DPP is a public-private partnership that offers evidence-based, cost-effective interventions to help prevent type 2 diabetes in communities across the United States. By working to increase the DPP’s appropriations, both directly and through our leadership in the Diabetes Advocacy Alliance, we are helping to ensure individuals in every state have access to this important program. We urge Congress to work with the Centers for Medicare and Medicaid

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<sup>3</sup> Chronic Disease Management Act of 2018 (H.R.4978/S. 2410).

<sup>4</sup> America’s Health Insurance Plans (AHIP). “2016 Survey of Health Savings Account – High Deductible Health Plans.” February 2017. [https://www.ahip.org/wp-content/uploads/2017/02/2016\\_HSASurvey\\_Draft\\_2.14.17.pdf](https://www.ahip.org/wp-content/uploads/2017/02/2016_HSASurvey_Draft_2.14.17.pdf).

<sup>5</sup> Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. 84 Fed. Reg. 2340 (Feb. 6, 2019).

Services to explore ways to encourage and increase provider participation in the DPP to ensure Medicare patients have access to these important interventions to help prevent type 2 diabetes.

At the state level, Novo Nordisk is an active advocate for legislation requiring states to develop data-driven diabetes action plans, which include policy recommendations from state Medicaid agencies and public health and state employee health benefits departments on how individuals at risk for diabetes can be better identified and how diagnosed patients can achieve better outcomes. Through Novo Nordisk's advocacy in collaboration with the American Diabetes Association, this legislation has been adopted in 23 states and has included funding recommendations for expanded access to evidence-based DPPs and reimbursement for diabetes self-management education.

#### *Conclusion*

It is time for all of us to do our part to ensure affordable access to insulin in the United States—not just to those for whom the system is working, but critically to those for whom the system is not working. Novo Nordisk pledges to be a part of that solution and to work with the Committee and others in our complex healthcare system to address the complicated landscape of laws, regulations, market forces, and supply-chain stakeholders that affect the price people pay for insulin. It is time for real change, and we look forward to being an effective partner with this Committee and others in Congress, the Administration, and the healthcare industry in that critical effort.

Ms. DEGETTE. Thank you.

Ms. Tregoning, now you are recognized for 5 minutes.

**STATEMENT OF KATHLEEN W. TREGONING**

Ms. TREGONING. Chair DeGette, Ranking Member Guthrie, and members of the subcommittee, thank you for the opportunity to appear before you today to discuss issues related to pricing, affordability, and patient access to insulins in the United States. I am Kathleen Tregoning, Executive Vice President External Affairs at Sanofi. My goal today is to have an open, transparent discussion about how the system works, Sanofi's role in it, and how it can be improved.

Patients are rightfully angry about rising out-of-pocket costs for many medicines and we all have a responsibility to address a system that is clearly failing too many people. As a mom, I was heartbroken at hearing the testimony before this subcommittee of other parents who have not only endured the terrible challenge of facing illness, but have also struggled to afford the medications that they or their children desperately need.

My own family is the beneficiary of a breakthrough in medicine. My husband, John, has FH, a genetic disorder that makes the body unable to remove LDL or bad cholesterol from the blood. He inherited this condition from his father who passed away from a heart attack at 40 years of age when John was just 12 years old. Despite taking statins, watching his diet, and exercising regularly, John, himself, had a double bypass at the age of 36 and still couldn't get his cholesterol under control. Then came a class of drugs called PCSK9 inhibitors, an innovative treatment that helps people like my husband lower their bad cholesterol.

I cannot overstate what this breakthrough means for him, our family, and our future, including for our 7-year-old son, Jack, who has inherited the same condition as his father and grandfather. I fully appreciate how important it is for science to continue to solve the medical challenges that impact so many families, and I recognize that those breakthroughs are meaningless if patients are not able to access or afford them.

Over the last 20 years, Sanofi has been a leader in the advancement of new treatments to help people manage their diabetes. At the same time, we recognize the need to address the very real challenges of affordability. Two years ago, Sanofi announced our progressive and industry-leading pricing principles. We made a pledge to keep list price increases at or below the U.S. National Health Expenditure Projected Growth Rate and we stand by this commitment. In 2018, our average aggregate list price increase in the United States was 4.6 percent, while the average aggregate net price, that is the actual price paid to Sanofi, declined by 8 percent, the 3rd consecutive year in which the amount we receive across all of our medicines went down.

Insulin is a clear example of the growing gap between list and net prices. Take Lantus, for example, our most prescribed insulin. The net price has fallen by over 30 percent since 2012, and today it is lower than it was in 2006. Yet, since 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients with commercial insurance and Medicare.

Every actor in the system has a role to play and Sanofi takes our responsibility very seriously. In addition to our pricing policy, we have developed assistance programs to help patients afford their Sanofi insulin, including copay assistance for commercially insured patients, including those in high-deductible health plans, and free insulin for uninsured low-income patients. Sanofi's commitment to patient affordability means that today approximately 75 percent of all patients taking Sanofi insulin pay less than \$50 a month.

But we recognized that more needed to be done. Last year, Sanofi launched a unique program that allowed individuals exposed to high retail prices to access Sanofi insulins for \$99 per vial, the lowest available cash price in the United States. Based on feedback from patients, providers, and the advocacy community, today we announced that we are expanding this program. Beginning in June, uninsured patients regardless of income level will be able to access any combination of the Sanofi insulin they need for \$99 per month at the pharmacy counter.

This transformative and first-of-its-kind program is the latest in a series of progressive and important steps Sanofi has taken to help patients afford the insulin they need. This action does not eliminate the need for broader system reform. I agree with the witnesses from last week's subcommittee hearing that holistic reforms to the system are not only needed but overdue. Sanofi also supports a number of recommendations outlined in my written testimony including many of the policies included in Chair DeGette's Congressional Diabetes Caucus report.

Thank you for the invitation and I look forward to answering your questions.

[The prepared statement of Ms. Tregoning follows:]

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**Testimony of Kathleen W. Tregoning  
Executive Vice President, External Affairs  
Sanofi**

**Before the House Energy and Commerce Subcommittee on  
Oversight and Investigations  
April 10, 2019**

Chair DeGette, Ranking Member Guthrie, and Members of the Subcommittee, thank you for the opportunity to appear before the House Energy and Commerce Subcommittee on Oversight and Investigations to discuss issues related to pricing, affordability, and patient access to insulin in the United States.

I am Kathleen Tregoning, Executive Vice President, External Affairs, at Sanofi. I am here today to have an open discussion about the current system for pricing and accessing insulin in the U.S., the actions we have taken to improve patient access and affordability to insulin, and our ideas about what more can be done.

At Sanofi, we work passionately every day to understand and address the health care needs of patients around the world. We are dedicated to solving patients' most serious health challenges in numerous therapeutic areas, including diabetes, cardiovascular disease, immunology, oncology, multiple sclerosis (MS), rare diseases, and rare blood disorders. We are also devoted to preventing diseases through the research, development, and delivery of vaccines. And we contribute to improving the health of people around the world through our broad portfolio of consumer health products.

Sanofi has a rich history in the United States dating back over 100 years. We currently employ more than 13,000 professionals across the United States in a broad range of critical roles, including business operations, research and development, and manufacturing. Our most significant U.S. presence is in Massachusetts, where we are the largest employer in the life sciences industry, and New Jersey, home to our U.S. headquarters. We also have major business, manufacturing and R&D operations in Pennsylvania and Tennessee.

Last year, Sanofi spent almost \$7 billion globally on research and development, an increase of approximately 7 percent from 2017, which reflects our commitment to bringing better therapies to patients. Sanofi plans to maintain this level of R&D investment through 2021, and our R&D pipeline now contains 81 projects, including 33 new molecular entities in clinical development, and 35 projects that are in Phase III or have been submitted to regulatory authorities. This investment means that Sanofi potentially will seek approval for nine new

medications in the next three years, primarily in therapeutic areas where Sanofi sees the greatest nexus between our expertise and patient need: diabetes, vaccines, oncology, immunology, rare diseases, and rare blood disorders.

Our work in R&D includes more than a dozen compounds for the treatment of various kinds of cancers, and we are employing cutting-edge approaches in an effort to make significant advances for patients. Our research includes potential treatments to help the body's own immune system fight cancer, and antibody drug conjugates that we believe can deliver cytotoxic drugs to tumors while sparing normal tissue. Just last month we announced successful results with one such candidate in a mid-stage trial in lung cancer, and we intend to initiate a pivotal study later this year.

I. Evolution of Insulins

Sanofi's innovations in diabetes, and, specifically, for insulin, have been significant.

The earliest insulin preparations were limited by their short duration of action, requiring patients to inject themselves multiple times a day and wake up at night for injections in order to control blood glucose levels. Each such injection of insulin caused a sharp spike in the patient's insulin levels, which could cause symptoms of low blood sugar ranging from shakiness and confusion to, in the extreme, coma or death. Injections also had to be timed before every meal, disrupting patient's lives, sleep times, and ability to eat with friends and family. As such, the consistent goals of insulin therapy over the last century have included reducing the frequency of insulin administration and flattening the post-administration peak of insulin in the bloodstream. Prior attempts to achieve these goals included cumbersome mechanical pumps that had to be worn on the body for constant infusion, and NPH insulin, which had an intermediate duration of action but still caused a pronounced peak in insulin levels.

The discovery and development of glargine changed all of that. Sanofi scientists succeeded in fundamentally altering the human insulin molecule at the amino acid level, changing its pharmacological characteristics to give patients a steady release of insulin with just a single daily administration. Unlike anything that came before it, glargine forms tiny solid crystals upon injection that dissipate over time to provide a flatter, stable, long-lasting effect that mimics the flat profile of insulin release from a healthy pancreas and reduces the risks caused by low blood sugar. The once-daily administration of glargine also provided a significant boon to patient lifestyles. The FDA first approved insulin glargine under the tradename Lantus® in 2000. Since its launch, Lantus has been studied in more than 90 million patient lives. Sanofi went above and beyond the regulatory authorities' approval requirements and conducted the first large Cardiovascular Outcome trial (CVOT - (ORIGIN)), to demonstrate the cardiovascular effects of an antidiabetic drug. Sanofi sponsored over 200 clinical trials, with more than 200,000 patients treated, resulting in over 2000 peer reviewed publications.

Since its discovery of insulin glargine, Sanofi has developed a new glargine formulation and a combination product to meet individual patient needs. While Lantus® provides significant

improvement for long acting (basal) insulin, for some patients, Lantus does not provide sufficient 24-hour basal insulin coverage. For other patients using higher doses, Lantus has a peak of action, which could lead to hypoglycemia. In order to more closely mimic endogenous basal insulin secretion, and to help type 2 diabetes patients meet their glycemic goals, Sanofi developed a next generation basal insulin, Toujeo®. Approved by the FDA in 2015, Toujeo provides an improved therapeutic effect at a higher concentration of glargine and exhibits a different and longer-acting profile than Lantus®.

Recognizing that approximately half of patients treated with basal insulin were still not achieving their blood glucose (HbA1c) targets, Sanofi launched Soliqua 100/33® in 2017. Intended for adults whose Type 2 diabetes is inadequately controlled on basal insulin or an oral antidiabetic medicine, Soliqua is a fixed ratio combination of Lantus and a non-insulin glucagon-like peptide receptor agonist (GLP-1 RA) that starts working after eating a meal. GLP-1s have been shown to reduce post-mealtime glucose peaks, which have been linked to cardiovascular disease in patients with diabetes; however, their use has been limited by gastrointestinal (GI) side effects. Soliqua has demonstrated reduction in average and overall glucose levels and reduction in GI side effects, with similar rates of hypoglycemia – thus allowing balance of lowered glucose levels without more hypoglycemia. Moreover, Soliqua has been found to have a beneficial effect on body weight, addressing one of the unwanted side effects of insulin.

These three products are among five insulin products currently manufactured by Sanofi.

In 2000, Lantus launched in a vial, so patients needed to inject the product with a syringe. Since that time, we have developed several more convenient injection devices for administering insulin. Our latest pen delivery system, SoloSTAR®, has been a key improvement in easing the daily burden of insulin administration for patients. Sanofi partnered with premier design firms to develop this pre-filled, disposable injection pen for self-administration that has improved the lifestyle and medication compliance of millions of diabetes patients. The SoloSTAR contains numerous features specifically designed to address the needs of people with diabetes, who often have health complications such as impaired vision and reduced dexterity. The pen's features include a clutch that couples and decouples complex internal mechanisms from each other to allow patients to "dial up" a dose for injection; dose dial stops that prevent patients from setting an excessive dose; a rotating dial that can easily correct an over-dialed dose; and a specially designed injection button that is easy for people with diabetes to depress and receive a highly accurate delivery of the set dose. All of the pen's complex mechanical features and parts were seamlessly incorporated into the SoloSTAR's design, while still providing a robust and reliable feel suitable for daily use by patients with a chronic condition. Sanofi launched the Lantus SoloSTAR in 2007, and it very quickly became the gold standard for pre-filled, disposable injection pens. It has won awards for its novel design.

Sanofi developed Toujeo SoloStar with several innovative design features and attributes, ranging from the length of time it can be held without overheating the contents, to other ergonomic features designed to make the pen delivery system easier to use. Additionally, Sanofi developed SoloStar Max®, which holds more units in the reservoir (900 vs 450) and gives

the patient the ability to dose up to 180 units in one injection vs the 80 units in the SoloSTAR pen, allowing for fewer injections and potentially for fewer refills and related copays.

We continue to study the safety and efficacy of our products for higher risk patient populations who would benefit from the more stable pharmacokinetic and pharmacodynamic profile, such as children and geriatric patients with diabetes. Sanofi understands that randomized clinical trials do not always provide a full picture of patient outcomes, so we have launched one of the most comprehensive real world evidence studies for a diabetes medication in the United States. We are studying Toujeo in diverse settings, ranging from a randomized, pragmatic prospective trial to predictive analytics and machine learning applied to large patient datasets. We believe that studying our medications in real world settings will continue to help drive needed innovation in diabetes treatment.

Looking to the future, our scientists are working on ways to potentially transform diabetes care by treating the underlying disease. To this end, Sanofi has a multi-pronged approach, through which we seek to prevent the progression of diabetes to insulin-dependence or restore insulin-producing cells through stem cell technologies. In addition, we recognize that the greatest contributor to the current diabetes epidemic is obesity. Our researchers are exploring the molecular mechanisms by which obesity leads to diabetes, and working to design molecules that aim to restore healthy metabolism and thereby stop diabetes in its tracks. This type of research, and the development of these new technologies, takes many years, and we continue to invest in these projects with the hope that we can eventually transform the lives of these patients.

## II. Rising Costs of Insulin for Patients

While the treatment of diabetes has been transformed by medical innovations, including multiple new discoveries to improve the quality and delivery of insulin, the landscape in which patients access medications has also fundamentally changed, and not for the better. We understand the anger of patients who cannot afford the insulin they need due to rising out-of-pocket drug costs.

In order to develop meaningful solutions for patients, it is critical to take a comprehensive look at what is driving rising costs for patients. Given the number of factors that contribute to determining out-of-pocket costs for patients, every actor of the supply chain, including manufacturers, has a role to play in solving this problem.

We want everyone – including patients, providers, payers, pharmacy benefit managers (PBMs), policy makers, and regulators – to understand why we set prices as we do, and we want to reaffirm our commitment to our core principles of access, affordability and innovation.

While list prices of medicines often receive the most attention, they reflect the initial price we set for our medicines. The list price is not the amount Sanofi receives or the price typically paid by government and commercial insurers, employers, or PBMs. Under the current system,

players within the supply chain – including PBMs, plans, wholesalers, distributors, and group purchasing organizations – receive either rebates and/or fees based on a percentage of the list price. Their economic incentives are therefore directly linked to the list price. As long as the net price grows at a predictable rate or even decreases, the greater the list price, the greater the economic returns for many players in the supply chain.

List price is the starting point for negotiations with payers and sometimes impacts patient out-of-pocket costs. But focusing solely on the list price does not tell the whole story. In the current system, manufacturers pay significant rebates as a percentage of the list price to government and private payers, as well as other intermediaries, in an effort to improve access for patients. As described later in my testimony, due to these rebates, the average aggregate net price of our products, including our insulin products, has declined over the last several years.

In some cases, affordability issues are the result of changes in health plan designs, such as the increase in the number of high deductible health plans (HDHPs). Among those with private health insurance, enrollment in HDHPs has increased since 2010. The design of these plans generally requires patients to pay the full list price of medicines during the deductible phase of the program, rather than the negotiated drug price available in the insurance portion of the plan.

In other cases, affordability issues are caused by changes in insurance design, which increasingly require patients to pay higher cost-sharing amounts for their medicines, even when the prices of those medicines have stayed relatively flat or declined for the health plan. For example, the average net price of Lantus, our most prescribed insulin, has declined by over 30 percent since 2012, while the average out-of-pocket burden for patients with commercial insurance and Medicare has increased by approximately 60 percent over that same period. In this case, not only are discounts apparently not being passed on to patients, but patients are in fact being asked to pay more when PBMs and health plans are paying less for the medicine.

Increasing out-of-pocket costs also can result from changes to prescription drug formularies, which have a significant impact on the amount of out-of-pocket costs a patient will be asked to pay. A recent opinion piece in the New York Times<sup>1</sup> highlights how changes to prescription drug formularies can not only create confusion and frustration for providers and patients but also ultimately increase costs for patients when the medicines they need are not covered on a formulary's preferred tier.

Sanofi provides rebates to PBMs and health plans to improve patient access to, and affordability for, Sanofi insulins. We want these rebates, which have grown in recent years and have resulted in substantially lower net prices, to benefit patients. Unfortunately, under the current system, savings from insulin rebates are not consistently passed through to patients in the form of lower deductibles, co-payments or coinsurance amounts.

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<sup>1</sup> See <https://www.nytimes.com/2019/01/18/opinion/cost-insurance-diabetes-insulin.html>.

Given the complexity in the system and number of factors that impact out-of-pocket costs, every part of the health care system has an obligation to work to solve this problem. I appreciate that this Subcommittee is taking a holistic approach to collecting information on what is causing the problem for patients. As we consider solutions to address patient access and affordability, it is essential that we not undermine the incentives and rewards for scientific risk-taking and discovery that are the hallmark of the United States ecosystem and economy.

III. Sanofi Actions to Improve Patient Access & Affordability

As a global health care leader, Sanofi has a long-standing commitment to promoting health care systems and policies that make our insulins accessible and affordable to patients in need. We believe we can play an important role in the development of constructive solutions that will benefit both patients and the healthcare system as a whole.

Sanofi is – and will continue to be – an industry leader in helping to address this challenge. While many factors, including decisions affecting patient out-of-pocket spending and insurance coverage, are influenced or controlled by others in the health care system, we recognize that there are actions we can take to help improve access and affordability for patients.

For our part, we recognize that we must price our medicines transparently and according to their value, while at the same time contributing to broader solutions that improve patient outcomes and the financial sustainability of the U.S. health care system. That is why in May 2017 Sanofi announced our progressive and industry-leading pricing principles to help stakeholders understand our pricing decisions and to advance a more informed discussion of issues related to the pricing of medicines.<sup>2</sup>

These principles include a pledge to keep annual list price increases at or below the projected U.S. National Health Expenditure (NHE) growth rate, an estimate of medical spending calculated by the Centers for Medicare and Medicaid Services (CMS) and often used as a measure of healthcare inflation. These principles apply to all of our prescription medicines if a price increase results in more than a \$15 annual increase in the price of the medication. In addition, we committed to making both our average aggregate list and net price changes across our portfolio transparent to help illustrate how revenue accrues to Sanofi versus other parts of the pharmaceutical supply chain.

In 2018, all of our price increases were consistent with our principles, as are all pricing actions we have taken in 2019. Across our entire portfolio of medicines, the average aggregate list price increase was 4.6 percent while the average aggregate net price – that is, the actual price paid to Sanofi – declined by 8.0 percent.

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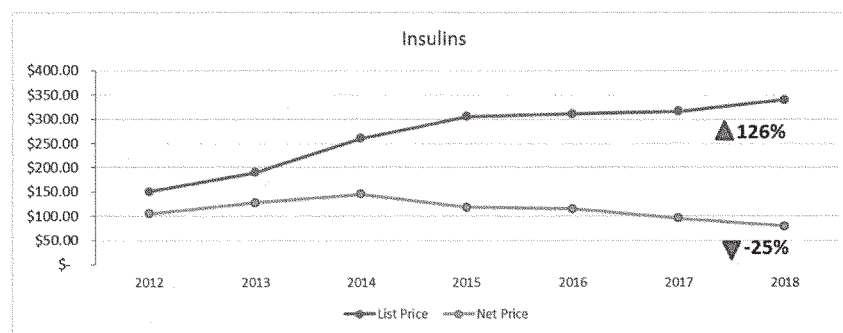
<sup>2</sup> See [https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Prescription\\_Medicine\\_Pricing\\_2019.pdf](https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Prescription_Medicine_Pricing_2019.pdf)

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The declining average aggregate net price in 2018 represents the third consecutive year the amount that health plans and PBMs pay Sanofi for our medicines has declined.

Specific to insulin, the average aggregate net price across all Sanofi insulin products has declined for the past four years, and based on existing contracts, will fall again in 2019. **For our entire insulin portfolio, the average net price is 25 percent lower today than it was in 2012.**<sup>3</sup>

**Sanofi Insulins List vs. Net Price Changes<sup>4</sup> Between 2012-2018**



When considering the patient access and affordability challenges of insulin, it is important to not only look at list price changes over time, but also net price changes. For example, Lantus, our oldest and most prescribed insulin, is frequently cited in stories about increasing insulin prices. While the list price of Lantus has increased significantly since it was approved, the net price – the amount Sanofi receives after discounts and rebates – has been declining for several years. In fact, the net price of Lantus today is lower than it was in 2006.

Unfortunately, competition among various diabetes treatments, and the resulting insulin net price declines, has not resulted in lower out-of-pocket costs for patients. As noted previously in my testimony, while the net price of Lantus has declined by over 30% since 2012, out-of-pocket costs for patients with commercial insurance and Medicare Part D have increased by approximately 60% over that same period of time.

In addition to our pledge to limit price increases in the U.S., Sanofi's pricing principles include a commitment to transparency in how we price new medicines coming to the market for the first time.

<sup>3</sup> Based on internal review of pricing actions and payer contracting.

<sup>4</sup> List Prices are calculated by dividing Gross Sales (sales at List Prices before discounts and rebates) by total trade units sold. Net prices calculated by dividing Net Sales (sales after discounts and rebates) by total trade units sold.

When we set the price of a new medicine, we hold ourselves to a rigorous and structured process that includes consultation with external stakeholders and considers four factors:

- 1) A holistic assessment of value, including: (a) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to a standard of care; (b) economic value, or how the medicine reduces the need – and therefore costs – of other health care interventions; and (c) social value, or how the medicine contributes to quality of life and productivity. Our assessments rely on a range of internal and external methodologies, including health technology assessment (HTA) approaches and other analyses that help define or quantify value and include patient perspectives and priorities.
- 2) Similar treatment options available or anticipated at the time of launch in order to understand the competitive landscape within the disease areas in which the medicine may be used.
- 3) Affordability, including the steps we must take to promote access for patients and contribute to a more sustainable system for payers and health care delivery systems.
- 4) Unique factors specific to the medicine at the time of launch. For example, we may need to support ongoing clinical trials (including longer-term outcomes studies), implement important regulatory commitments, or develop sophisticated patient support tools that improve care management and help decrease the total cost of care.

Applying these methodologies, Sanofi has launched a number of innovative products at prices well below the competition. In the insulin space, we launched, and are committed to maintaining, Admelog<sup>®</sup>, a biosimilar of insulin lispro, at the lowest list price of any mealtime insulin.

With the right incentives in the system, our approach to setting launch prices for these new medicines coupled with our limit on list price increases should have had the effect of ensuring affordable access for patients.

#### Sanofi Patient Support Programs

Sanofi has adopted a variety of approaches to work within the current system to improve access and affordability of insulin for patients. We have developed some of the most forward leaning programs to help patients afford Sanofi's insulin products.

Commercially insured patients qualify for our co-pay assistance program, regardless of income, which reduces the financial burden for insulin products. Through this program, over 90% of participating patients pay either \$10 or \$0 per month for their Sanofi insulin. While current regulations prohibit us from offering this type of program to patients insured under Medicare

or similar federal or state programs, Sanofi supports efforts that would expand this access program to all those who might benefit.

Additionally, we created the Insulin Val~~y~~**you** Savings Program in 2018. The intent of the Insulin Val~~y~~**you** Savings Program is to provide relief for those who currently pay high variable retail prices for their insulin and do not qualify for other assistance programs. Through this program, eligible individuals can access all Sanofi insulins for \$99 per 10 mL vial or \$149 for a pack of SoloStar pens – roughly a one-month supply – at a discount of up to 60 percent below the list price, resulting in savings of up to \$3,000 per year. There are no income requirements, and the program is available at U.S. pharmacies. Since it was launched last April, the program has resulted in approximately \$10 million in patient savings.

For eligible uninsured and underinsured low-income patients, including Medicare patients, Sanofi offers many of our medicines, including our insulin products, at no charge through its Sanofi Patient Connection patient assistance program. We are proud that, in 2018, more than 93,000 patients participated in the Sanofi Patient Connection program.

Despite the many challenges and perverse incentives that exist in our health care system, Sanofi's commitment to patient affordability means that today, approximately 75 percent of all patients taking Sanofi insulin pay less than \$50 per month. We believe many others may be eligible for one of these programs to reduce their costs, and we continue to promote these programs to raise awareness about the support that is available.

Last week, Sanofi joined other insulin manufacturers to fund a program that limits insulin co-pays to \$25 for patients covered under ESI and Cigna plans. While this out-of-pocket maximum is greater than patients may pay if they enroll directly in Sanofi's co-pay assistance program, which may reduce a commercially insured patient's out-of-pocket burden to as low as \$0, we believe this new initiative launched by ESI and Cigna will unquestionably lower out-of-pocket costs for some patients.

#### IV. Solutions

I am proud of Sanofi's leadership to help improve access and affordability to insulin products for patients. However, despite the actions we have taken, on behalf of everyone at Sanofi, I know more needs to be done. My testimony today is intended to provide a more transparent and open picture into the system surrounding access to insulin therapies in order to enable this Subcommittee to consider a common set of facts and design solutions to meet urgent patient needs. I hope we can all agree on market-based policy solutions that will incentivize a high-value, highly competitive, and sustainable health care system that improves the affordability of innovative medicines in the U.S.

It is my belief that targeting list price alone will not be sufficient to address patient access and affordability. Just lowering list prices, without guarantees that those lower-priced medicines would be included on formularies at affordable, low co-pay tiers may not solve the problem for

most patients. Sanofi's Insulin Valyou savings program offers significantly less expensive access to all of our insulin products even when compared to recent actions by others to lower list prices. The solution to insulin access and affordability must include protections for patients, tying responsible pricing to both access and affordability.

There are a variety of ways to accomplish this goal, and Sanofi could support any number of options that align to our core principles:

- 1) The U.S. should continue to maintain a strong ecosystem for innovation. As such, any policy proposals should strictly avoid directly and artificially controlling the price of medicines, either through price controls set by the federal government, or worse, outsourcing that decision to other governments. Policy proposals that we believe would fundamentally undermine the unique innovation ecosystem of the United States include reference pricing, importation, or price controls set by CMS.

Based on our experience in other countries, these approaches may be effective at controlling budgets for central payers, but come at a steep cost for patients – namely limiting access to innovative treatments. Additionally, given that the U.S. is the world's leader in science and innovation – and the jobs that come with it – these approaches pose additional risks to the U.S. economy and future scientific discovery. Finally, and most importantly, given the differences between systems, these approaches may do little to improve access and affordability for patients.

As we have experienced, within the current system, declining prices for payers or new treatments priced at responsibly lower list prices are no guarantee that those actions will translate to affordability or access for patients.

- 2) Changes to the pricing system must be holistic, and the benefits should accrue to patients. As noted previously, simply enacting price controls will not solve the problem of access and affordability for patients. We believe system incentives need to change to encourage smaller list price increases, or list price reductions, by requiring health plans to cover those medicines that meet these standards at affordable co-pay levels and only allow access restrictions consistent with the product label and accepted evidence-based best clinical practice.

If policies solely target the list price of medicines without these common-sense patient protections, our shared goal of lowering insulin costs – for both government and patients – while maintaining the engine of innovation in the United States to bring innovative medicines to patients will not be fully achieved. To appropriately accomplish our shared objective of greater access and affordability for patients, Sanofi is willing to contribute our fair share to offset any financial impact to the health care system as long as patient access and affordability are improved for all patients.

Sanofi supports and recommends several policy solutions to incentivize responsible pricing behavior. To ensure that these changes do not create a windfall for manufacturers or health plans and PBMs, Sanofi recommends applying these policies only to medicines that satisfy certain limits on price increases. This approach will shift the current incentives in the system to reward “good” behavior in a manner that truly helps patients. Several of the solutions outlined below are also priorities for Members of this subcommittee and I look forward to the opportunity to work with you on advancing these and other policy initiatives:

First, reducing out-of-pocket costs for patients is our top priority. Sanofi has identified a number of ways to effectively reduce out-of-pocket costs for consumers and broadly supports tradeoffs between price and access to help patients, including the following:

- Whether through legislation, implementation of the Anti-Kickback Safe Harbor rebate proposed rule, or changes in market dynamics, link lower list prices to improved access and affordability for patients.
- All payments in the supply chain should be de-linked from list price, which would remove the perverse incentive that sometimes feeds the cycle of higher list prices paired with higher rebates.
- Require a substantial portion of the discounts and rebates paid by manufacturers to reduce costs for patients at the pharmacy counter.
- Change government price reporting rules and the Anti-Kickback statute in a manner that would promote value-based contracting.
- Implement an annual out-of-pocket cap for Medicare beneficiaries.
- Allow Medicare beneficiaries to access manufacturer co-pay assistance programs.
- Change or clarify government price reporting rules to make it easier to reduce list prices on medicines that have been on the market for a long time – namely by (1) making clear that the government pricing metrics for the new, lower list price drug do not have to be averaged with the metrics for older, higher list price drug and (2) permitting a company to treat the new lower price drug as a new product for purposes of Medicaid rebate calculations, which will help to link the rebate liability for the new drug to the new drug’s lower price as opposed to the higher price for the old drug.

Second, Sanofi supports policies that further cultivate a highly competitive free market system and reward the type of entrepreneurial risk-taking necessary to the discovery and development of life-saving new medicines. A key element of that system is strong and predictable intellectual property protection. However, after a reasonable period of time – which I believe is already reflected in U.S. law – generic and biosimilar medicines should quickly enter the market to offer long-term access at lower costs. To help accomplish these goals, Sanofi supports:

- Increasing competition among medicines. Whether through prohibiting “reverse payment” patent settlements, requiring timely access to samples for generic or biosimilar manufacturers, establishing a clear patent listing of biologics through a “Purple Book”, or further encouraging the development of biosimilar insulin products, Sanofi supports robust competition to encourage continued development of life-saving medicines. At Sanofi, we make product supply available to generic and biosimilar manufacturers developing data necessary for FDA applications for their products. We do this in a timely manner and on commercially reasonable terms. We support both the CREATES Act and the Purple Book Continuity Act as passed out of the full Committee last week.
- Increasing system-wide transparency, which would improve competition by making relevant information available to patients and policymakers. Providing more information about what is driving costs in the system and how money is flowing through the system will allow for increased competition and better-informed decision making. Policies that include price reporting requirements to incentivize responsible pricing behavior have the potential to change current practices, but they should be modified to protect confidential information and preempt similar state law policies in order to create a single set of requirements.
- Requiring health plans and PBMs to disclose an annual list of medicines for which the net price has decreased, as well as how the decrease (or value generated by it) was allocated among the health plans, PBMs, government payer, and patients.

Finally, Sanofi supports many of the recommendations made by the Congressional Diabetes Caucus in its whitepaper<sup>5</sup> entitled: “Insulin: A lifesaving drug too often out of reach,” including the following:

- Encourage the development and use of value-based contracts between insulin makers and PBMs.
- Promote the use of payment arrangements between insulin makers and wholesalers that involve standardized fees instead of rebates.
- Require insulin makers, PBMs, and health insurers to disclose the value and volume of rebates that they receive and share with other entities in the insulin supply chain.
- Link patient out-of-pocket costs to negotiated prices instead of list prices.
- Allow generic manufacturers to produce older, off-patent insulin formulations.
- Require manufacturers to disclose their insulin’s list pricing process.

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<sup>5</sup> <https://diabetescaucus-degette.house.gov/sites/diabetescaucus.house.gov/files/Congressional%20Diabetes%20Caucus%20Insulin%20Inquiry%20Whitepaper%20FINAL%20VERSION.pdf>

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- Standardize the process for requesting exemptions or filing appeals from formulary changes.
- Standardize drug formulary disclosure of patient cost-sharing information.
- Limit the number of changes an insurer is permitted to make to a formulary each year.
- Cap out-of-pocket expenses for prescription drugs that are needed for chronic conditions.

V. Conclusion

I look forward to having a productive conversation about the complexities of the current prescription drug pricing system and proposals to improve affordable patient access to high quality, innovative life-saving medications such as insulin to drive optimal health outcomes.

Thank you for the invitation to speak with you today and I look forward to working with you.

Ms. DEGETTE. Thank you, Dr. Dutta.

It is now time for the Members to ask questions and the Chair recognizes herself for 5 minutes.

I appreciate all of your testimony. What strikes all of us on this panel, which we have heard from all of the actors in the system, is how the list price is really high, but then there are all these workarounds that some people can get to get a lower price of insulin, and let me just give you an example. Eli Lilly increased the price of Humalog from \$35 in 2001 to \$275 today. Novo Nordisk increased the list of NovoLog by over 350 percent since 2001. And on January 8th of this year, the insulin products of Novo Nordisk went up by 5 percent. Sanofi increased the price of Apidra from \$86 in 2009 to \$270 last year. And so, since January 1st, the three main brands were 4.4 to 5.2 percent gone up this year.

And most everybody here now knows my daughter Francesca, who is 25, she is a type 1 diabetic. I am not going to put anybody on the spot, but she is on a newer kind of insulin and she has insurance. She is still on my insurance for eight more months—who is counting—and she renewed her prescription at the beginning of the year. And for this insulin it says on the receipt the retail price, \$1,739.79, “Your insurance saved you 1,399.79.” But for her type of insulin she is on, the list price is \$347.80 per bottle. Now she didn’t pay that because she is on insurance, but she still paid quite a bit because I have a pretty high deductible.

So here is the thing everybody is saying, “Well, sure the list price is high, but there are all these workarounds.” But not everybody gets the workarounds, and the question is why is the list price so high? So, I am going to ask each one of you, and I have really limited time.

Mr. Mason, I am wondering if you can tell me in 30 seconds, how does Eli Lilly justify these huge increases in list prices in the past 10 or so years?

Mr. MASON. Thank you for the question. I hope your daughter is doing well.

Ms. DEGETTE. Yes, forget about that. Just, please.

Mr. MASON. Seventy-five percent of our list price is paid for rebates and discounts to secure access, so people have affordable access——

Ms. DEGETTE. That is what is making the price go up and up?

Mr. MASON. Two hundred and ten dollars of a vial of Humalog is paid for discounts and rebates.

Ms. DEGETTE. OK, Mr. Langa, same question.

Mr. LANGA. So as you heard last week from Dr. Cefalu from the ADA, there is this perverse incentive and misaligned incentives and this encouragement to keep list prices high, and we’ve been participating in that system because the higher the list price, the higher the rebate.

Ms. DEGETTE. So, you also think it is because the rebates that the prices have gone up so much in the last 10 years?

Mr. LANGA. There’s a significant demand for rebates. We spend almost \$18 billion.

Ms. DEGETTE. OK, I am sorry.

Ms. TREGONING. Yes, as part of how we set list prices, we have to look at the dynamics of the supply chain including the rebates.

We have at Sanofi limited ourselves to list price increases no greater than national health expenditures across every one of our products.

Ms. DEGETTE. OK.

OK, now, Mr. Moriarty, I bet you have a different perspective on why the list price of insulin is so high.

Mr. MORIARTY. Chairwoman, rebates are discounts. And as we've disclosed, more than 98 percent of those discounts go back to our clients.

Ms. DEGETTE. I understand, but why do you think the list prices are so high?

Mr. MORIARTY. I can't answer that. That is the pharmaceutical manufacturers' purview.

Ms. DEGETTE. But you don't think it is because of discounts?

Mr. MORIARTY. I do not, no.

Ms. DEGETTE. Ms. Bricker?

Ms. BRICKER. I concur. I have no idea why list prices are high and it's not a result of rebate.

Ms. DEGETTE. Dr. Dutta?

Dr. DUTTA. We see list prices rising double digits in non-rebated drugs, in generics where monopolies lost, or where manufacturers buy up and create monopoly, so we can't see a correlation just when rebates raise list prices.

Ms. DEGETTE. OK, so of course my time is almost up, but I think this is a good example of the problem that the Members of Congress are dealing with in trying to figure out how to solve this problem. Because it seems to me what is happening is that every component of the drug system is contributing to an upward pressure on the list price.

I know the members are going to have a lot of questions around that and we will do some follow-up at the end, so I would like to recognize the ranking member for his input, for 5 minutes.

Mr. GUTHRIE. Thank you very much. Thanks for being here. I am going to use a quick example just because I am trying to make it simple. I have been wrestling with this for about a month in trying to figure out what is happening.

If Chair DeGette was making this phone and I want to buy it and she said she is willing to take \$100 for it, but she says, "I will sell it to you for 300," and give me 200 back, and that doesn't make sense. Or Chair DeGette is willing to take \$100 and I say to her, "Hey, I am willing to pay 100, but charge me 300 and I will give you 200 back." The whole idea is that Brittany is the purchaser at the end and I am passing, I am giving that to her for \$100 because she is the plan, she is saving the money and passing it on to her consumers, and what we are trying to figure out is where that delta is going. It is just hard to figure out and I have been spending a lot of time on it.

On February 6th, so the three manufacturers, I want to try to, because I have a few questions so try to go fast, you said that your list price has gone up, but your net price has gone down. What would happen if you just said, "Hey, I want to make my list price my net price, and put it out on the marketplace?"

So I'll let you three.

Mr. MASON. First of all, we are dropping our list price of Humalog by 50 percent with our launch of lispro insulin. For us there are many people who have access. The majority of people have access for insulin at affordable cost through their plans. That's not tied to list price, so we don't want to disrupt those by lowering list price. We think the best way is to provide in the short-term is to keep our list price at the way it is; so we don't disrupt those individuals, we don't harm the access that they have.

Mr. GUTHRIE. But if you are willing to take, I think you said you had, I don't know, whatever the net price is, I know net prices are different with different plans. There is not one net price, I get it. But if you are willing to take a net price for your product and three of you here, why wouldn't that be something out there for everyone to pay? I mean that is what you are willing to charge, right?

Mr. MASON. It's just more difficult to do that to disrupt that for a product that's on the marketplace today, because people have affordable access.

Mr. GUTHRIE. But you have had your net price and according to your testimony go up 207 percent while your list price dropped by 3 percent, according to the letter on February 6th on Humalog.

I think you all are similar too. I don't want to just do Lilly, all of you guys as well. I mean that is kind of, so we see the net price going—I understand what you are saying, but we see the net price rising. We want to know why it is doing it? Maybe there is a market reason for that and it is benefiting consumers, but we want to know.

Mr. LANGA. In the current system today, the most important thing for us is for the most number of patients to get our brands at the most affordable prices, and in the system today that is the current formulary positions. Just the three PBMs here today represent over 220 million covered lives.

Mr. GUTHRIE. OK, you said they were perverse. OK, I am running out of time.

Mr. LANGA. So that is 80 percent of the lives, so for us to lose one of those positions that would be a dramatic impact to patients in terms of the medicine that they are on, physicians in terms of their choice.

Mr. GUTHRIE. Your argument is——

Mr. LANGA. And there would be——

Mr. GUTHRIE [continuing]. You would lose your position on the formulary if you lowered your price?

Mr. LANGA. In the current system if we eliminated all the rebates, yes.

Mr. GUTHRIE. You are shaking your head, the same way?

Mr. LANGA. We believe that we would be in jeopardy of losing those positions.

Mr. GUTHRIE. You said there were perverse incentives. What are the perverse incentives?

Mr. LANGA. Well, we're spending almost \$18 billion a year in rebates, discount, and fees, and we have people with insurance with diabetes that don't get the benefit of that.

Mr. GUTHRIE. What are the perverse incentives for that 18 billion in rebates? You said they are perverse——

Mr. LANGA. They're going into the system and they're misaligned, right, so that's, we believe that they should go back to the diabetic patient.

Ms. TREGONING. The issue here, Congressman, is not one of negotiation. The PBMs are very effective negotiators. It's what happens with the results of that negotiation. Those rebates are not necessarily going all the way through to patients. They're being used for other parts of the system, and we don't have visibility to how those rebates get used. Those rebates are part of how we secure formulary placement and cost sharing for the patients that are covered by those plans.

Mr. GUTHRIE. So you say, "I am willing to take X for a product, but for me to get on their formulary, I know I am going to have to raise my list price because they then want rebates," is that what you are arguing?

Ms. TREGONING. The rebates are how the system has evolved. The rebates are part of the negotiation to secure formulary placement and associated—

Mr. GUTHRIE. I went too long on that side because I am not giving you—you already talked to that, I guess. I had other questions, but I would rather hear your responses to that.

Ms. BRICKER. So as mentioned previously by my colleague to my left, of course we're looking at the clinical attributes of a product and I know you want to get to the economics. The way we make formulary decisions is based on net price. If every one of the manufacturers to my right wanted to reduce their list price, there would be no implication to the rebate status so long as the net price remained the same.

Mr. GUTHRIE. So on my example, if she is willing to sell for me a hundred and I sell to Brittany for a hundred, and you are saying rebates keep the price down, but in the end because you are selling to her at the net price, so why wouldn't the net price be—what we are trying to figure out is it seems like there is a price that is marked through the system that seems to be based on something, but there seems to be an inflation and another higher price that just seems to be caught up in the system.

But what really affects people as we have talked about, when they are going to the point of sale when they haven't hit their deductible. I know you have these plans in place and those are great, but we need to figure out the economics behind it; so if we need to do something here to help people out, we need to understand that.

I wish we had more than 5 minutes. I yield back.

Ms. DEGETTE. The Chair recognizes Mr. Kennedy for 5 minutes.

Mr. KENNEDY. Thank you. I want to thank the witnesses here and I want to thank the Chair and ranking member for holding this hearing.

I am going to follow up on some of the questions that have already been asked. I want to submit for the record though a Boston Globe piece from last November. I have done this before in other hearings about individuals, two mothers that brought ashes of their children in front of Sanofi in Boston, in Cambridge, back in November trying to protest these prices.

You all have, you know why we are here, and you know what the challenges are. I can tell you even from being here for a couple minutes how frustrating it is to be on this side of the dais, and watch everyone do this. So I also, I hope, and I expect that you will also understand that if that is the result of this hearing that we are not, you are hearing bipartisan frustration on this. You are not going to—the status quo is not going to continue, it can't.

We heard testimony last week from patients that were literally rationing, putting their lives on hold, or taking serious risks for themselves and their children, to be able to get access to medicine that was patented and sold for a dollar.

And, sir, Mr. Mason, you began by saying about the 75 percent of that increase over the course of the past several years increase in list price goes to PBMs. The data that I have indicates that over the past—since 2002 to 2013, Endocrine today estimated the average price went from \$231 in 2002 to \$736 in 2013, inflation adjusted. Seventy-five percent of that is roughly \$375. That means 127—50 percent of that baseline price is not PBMs.

Where is the other 50 percent? What justifies the other \$127 increase?

Mr. MASON. You know, our net prices have gone down since 2019, so the—or since 2009. We haven't taken a price increase until since 2017.

Mr. KENNEDY. Sir, have you ever lowered a price off of your formulary?

Mr. MASON. We are launching a lower priced Humalog that's 50 percent off.

Mr. KENNEDY. It took 15 years and global outcry on this to do it? What factors go into—have you ever lowered the price off of a formulary?

Mr. MASON. We have lowered our net price over the last 10 years.

Mr. KENNEDY. What factor goes into lowering that price? What evaluation do you take to lower that price?

Mr. MASON. What evaluation, you know, a decade ago we were on formularies, all formularies, now we're on formularies about, you know, half, about half of formularies, patients in America have our insulins because we're moving to strictly formularies. We have to provide rebates in order to provide and compete for that so people can use our insulin.

Mr. KENNEDY. Mr. Langa, have you ever lowered a list price?

Mr. LANGA. We have not.

Mr. KENNEDY. Why not?

Mr. LANGA. For two reasons, as I said the biggest vehicle today for the most majority of patients in this country—

[Simultaneous speaking.]

Mr. LANGA. No, it's formulary position. So that's the best way for us today to reach the most amount of patients in an affordable way and anything that risks that is something that we have to strongly consider. Everything's on the table right now for Novo Nordisk. We want to be part of the solution.

Mr. KENNEDY. If it takes us hauling you in after people are telling us that they are rationing the lives of their children, how does this work? I understand that part of this comes back on us. You

guys are responding to incentives that Congress sets and a lack of regulation, a lack of oversight to allow this to happen. But from my position at the moment, trying to figure out what levers to push and pull, we are asking what goes into the factors to set that list price, we don't get an answer. To lower risk price, it either hasn't happened or we don't know. You place the blame on the major of the hike of it to going on the PBMs and the PBMs are putting it back at you.

If you were in my position, what do we do to try to make sure that patients in this country get access to lifesaving medication, that was initially discovered for a buck and sold to a university, to ensure that every person could get access to it? What do you suggest?

Mr. LANGA. I suggest that we all come together to come up with solutions, get together with Congress to make sure that rationing never happens again. As I mentioned in my opening statement, one patient is too many. And as an organization that's for 90 years been committed to patients with diabetes, it's tragic and it should never happen.

Mr. KENNEDY. Ms. Tregoning?

Ms. TREGONING. Congressman, no one should be rationing insulin. No one—

Mr. KENNEDY. And they do every day.

Ms. TREGONING. We need to make those patients more aware of the programs that are available.

Mr. KENNEDY. What do you do—the programs, ma'am, there were people here last week that said those programs take weeks to get into that there are not transparency on it. They can't wait six weeks to get an insulin shot.

Ms. TREGONING. Congressman, our copay assistance programs can be accessed in a matter of minutes online, and so, people with high-deductible health plans—

Mr. KENNEDY. Do you have any patients that don't have access to internet?

Ms. TREGONING. We also have phone numbers where patients can call.

Mr. KENNEDY. How long does it take for them to be able to access those programs? What percentage of folks do you deny?

Ms. TREGONING. For copay assistance and for—we have, it's literally a matter of moments for the VALyou Savings Program that we accessed, that we announced today, the expansion—

Mr. KENNEDY. That you announced today when you are in front of Congress?

Ms. TREGONING. It's an expansion of a program that we started last year, \$99 for the insulin that they need in any combination at the pharmacy counter; people can get access to that. It's for uninsured patients. For those with high-deductible health plans, they can access copay assistance that's no more than a \$10 copay.

Mr. KENNEDY. I am way over time.

But for the folks that are uninsured that are paying your full list price—

Ms. TREGONING. For the folks that are uninsured paying full list price—

Mr. KENNEDY. I yield back.

Ms. TREGONING [continuing]. They now have access as of June, \$99 at the pharmacy counter for the insulin that they need per month.

Ms. DEGETTE. The Chair recognizes the ranking member of the full committee, Mr. Walden, for 5 minutes.

Mr. WALDEN. Thanks again, Madam Chair, for having this hearing. Thanks again to our witnesses for being here.

Ms. Tregoning, in 2018, Sanofi launched Admelog. Now I understand that is a follow-on biologic to Eli Lilly's Humalog. Now according to press articles, Sanofi launched Admelog at a list price that is about 15 percent less than the list price for Humalog. Is that pretty close?

Ms. TREGONING. Yes. It's the lowest rapid-acting list priced insulin.

Mr. WALDEN. OK. Typically, when a generic medicine enters the market, we expect for the price of the generic to be less than the branded; and many patients to switch from the brand medicine to the generic medicine. You have told us, however, that Admelog is not on the formulary for any commercial plans. I believe that is correct?

Ms. TREGONING. No. Yes, correct. It's only available through Managed Medicaid.

Mr. WALDEN. Given that Admelog was launched at a lower list price than Humalog, what barriers are preventing patients from this alternative and are there issues gaining formulary access for Admelog?

Ms. TREGONING. Congressman, we were unable to secure formulary access through rebating with Admelog. As to exactly why those decisions were made, I'd have to defer to my colleagues on the other side of the panel.

Mr. WALDEN. Has Sanofi faced these barriers for launching any other products?

Ms. TREGONING. Yes, Sanofi has brought a number of products to patients at lower prices including Kevzara, which is a lower list price of a rheumatoid arthritis medicine, and we similarly face challenges.

Mr. WALDEN. Given Sanofi's experience with Admelog, do you think more follow-on biologics and biosimilars of insulin will help reduce the list price of insulin, or does the biologic market function differently than introduction of a generic of a small molecule drug?

Ms. TREGONING. There is already competition in the insulin market as I believe one of the colleagues referenced. Eli Lilly introduced a follow-on biologic version of Lantus several years ago and so there is competition. CVS in its testimony spoke to the fact that they were able to leverage greater rebates and negotiate through that.

Mr. WALDEN. Now, I want to switch to Mr. Mason and thanks again for being here. We have heard that sometimes a branded biologic manufacturer may tell pharmacy benefit managers, PBMs, and health insurance plans that they will no longer provide rebates for their branded product, if the PBM or health insurance plan puts a follow-on biologic or biosimilar on the formulary. Has Eli Lilly told any PBMs or health insurance plans that it will no longer

provide rebates for Humalog if the PBM or health insurance plan puts Admelog on its formulary?

Mr. MASON. No, we haven't.

Mr. WALDEN. All right.

Ms. Tregoning, similarly did Sanofi tell any PBMs or health insurance plans that it would stop providing rebates for Lantus if the PBM or health insurance plan put Basaglar on their formulary?

Ms. TREGONING. No, nothing.

Mr. WALDEN. Mr. Moriarty, has a manufacturer ever said they would stop providing you rebates for a product if you put a competing product on your formulary?

Mr. MORIARTY. Not that I'm aware of, sir.

Mr. WALDEN. OK, so that has never happened.

Mr. Moriarty, Ms. Bricker, and Mr. Dutta, why isn't Admelog included on your formulary?

Ms. BRICKER. The challenge that we have with Admelog specifically is one of net cost. And so through the mechanisms that we use today, which are rebates or discounts, it was more expensive than competing product. Manufacturers do give higher discounts for exclusive position, so I think that was your question to my counterpart here on the right.

Mr. WALDEN. Yes, if each of you could answer that.

Ms. BRICKER. Yes, so to the extent that we have recognized one product as exclusive, other manufacturers will—that exclusive product will receive less discount if additional products are added.

Mr. WALDEN. Why not include both?

Ms. BRICKER. We'll receive less discount in the event that we do that.

Mr. WALDEN. What?

What about the others on the panel, Mr. Dutta and Mr. Moriarty, can you speak to this?

Dr. DUTTA. The lowest cost product gets preferential position on our formulary. So, for example, generics which are very low cost have preferential position.

Mr. WALDEN. OK.

Mr. Moriarty?

Mr. MORIARTY. Similarly, we drive to lowest available cost, lowest cost product. And with the example of Basaglar we were able to move that follow-on biologic to preferred status and actually have most, if not all, patients now on that one.

Mr. WALDEN. We keep hearing the manufacturers should just lower their list prices, but a lower list price doesn't necessarily guarantee that a manufacturer will have access to patients, or that that patient will pay a lower price at the pharmacy counter. Do you take the list price of a medicine into consideration when making formulary decisions?

Mr. MORIARTY. We do not. We focus on the lowest available cost, the lowest net cost.

Mr. WALDEN. All right.

Ms. Bricker?

Ms. BRICKER. The same, yes, lowest net cost.

Mr. WALDEN. Mr. Dutta?

Dr. DUTTA. Lowest net cost, and for the member we consider their cost by using point-of-sale discounts and in order to lower their cost out-of-pocket.

Ms. DEGETTE. I just want to follow up on the ranking member's questions for Mr. Moriarty and Dr. Dutta. Why then if you look at generics and the lowest cost, why aren't either of your PBMs putting Admelog on these plans?

Mr. MORIARTY. Madam Chair, we have gone with Basaglar as the follow-on biologic alternative and the preferred status for that category.

Ms. DEGETTE. OK.

Dr. Dutta?

Dr. DUTTA. It would cost the payer more money to do that.

Ms. DEGETTE. Why?

Dr. DUTTA. Because the list price is not what the payer is paying. They're paying the net price.

Ms. DEGETTE. The Chair now recognizes Dr. Ruiz.

Mr. RUIZ. Thank you, Chairwoman.

The rising cost of drugs is such a big problem that it has reached kitchen table, family conversations across America. Those families are struggling, worried about having to decide between paying for insulin or paying their bills. There has been a lot of rhetoric today, and finger pointing in the drug pricing debate; and oftentimes the conversation is based on theoretical arguments about what will work for manufacturers, or PBMs, or insurance companies, with little regard to what works for patients.

As a doctor, I put my patients' needs above all else and our solutions should do the same and reduce out-of-pocket costs for patients. In my district, according to the Health Assessment & Research for Communities 2016 survey, one out of four adults diagnosed with diabetes in the Coachella Valley are living below the Federal poverty line; and over 10 percent of adults diagnosed with diabetes do not have health insurance that covers some or all of the cost of their prescription drugs. This is not just a problem for the uninsured or underinsured either.

Just this week I heard from Tamara Smith and David Richard, two constituents who had to go on a specialized form of insulin that isn't covered by their insurance. That means hundreds of dollars more out-of-pocket every month. So reducing the list prices of drugs or increasing the number of generics does not solve the problem, if these savings are not lowering out-of-pocket costs for people like Tamara and David. The CEO of Diabetes Patient Advocacy Coalition drove home this point in her testimony last week in stating, "Somebody's making a profit and it's not the patients."

So, Mr. Mason from Eli Lilly, who is making a profit from these increases in insulin prices?

Mr. MASON. You know, I think, first of all, we don't want anyone not to be able to afford their insulin.

Mr. RUIZ. Who is making a profit with these increases in insulin prices that patients have to pay for?

Mr. MASON. Our net price is the price that we receive are going down.

Mr. RUIZ. Are you?

Mr. MASON. No.

Mr. RUIZ. Are you making a profit? Are the CEOs of your companies making these profits?

Mr. MASON. Our net prices, the price that we receive has gone down since 2009.

Mr. RUIZ. Well, somebody is making a profit. Somebody is getting richer on the backs of our patients.

Mr. Langa from Novo Nordisk, what entity in the supply chain is prioritizing affordability and access of insulin for patients?

Mr. Langa. Well, we'd like to think we are. I mean we participate in as many formularies as we can. As I've mentioned that is critically most important. We have Patient Assistance Programs as well as copay assistance programs.

Mr. RUIZ. Who is making a profit then?

Mr. Langa. Well, our nets are going down as well, but there is a small profit that—

Mr. RUIZ. Your nets, but your overall profits for the company and CEOs have been going up, haven't they?

Mr. Langa. No. Our profit has been—

Mr. RUIZ. Take-home pay from CEOs?

Mr. Langa. Our profits have been relatively stable.

Mr. RUIZ. From CEO pay hasn't gone up in the past several years?

Mr. Langa. His pay has increased, yes.

Mr. RUIZ. OK.

So last week, Dr. Cefalu from the American Diabetes Association noted that PBMs' primary customers are the health plans and insurers not the patients. He testified, "We don't know whether those transactions are actually benefiting the patient at the point of sale."

Ms. Bricker from Express Scripts, does Express Scripts pass any savings on to beneficiaries; and how do we know what the difference is if there is not that transparency?

Ms. BRICKER. So yes, thank you for the question. For over 20 years, Express Scripts has supported point-of-sale rebates. We do have clients and plan sponsors that are—

Mr. RUIZ. How do we know what the percentage of that cost savings to patients, is if we don't have transparency of what the savings are? Are they going to your clients' profit or are they going to reducing out-of-pocket costs? How do we know?

Ms. BRICKER. So we support transparency for our plan sponsors, those that hire us. They absolutely have the ability to look at all of our rebate negotiated contracts as well as our retail contracts. We believe in transparency for patients.

Mr. RUIZ. So we need to look into what you say, and what is actually being done with implementation and that is what the purpose of this is for.

Mr. Moriarty from CVS Health, are these barriers to passing discounts on to patients at the point of sale and, if so, what are they?

Mr. MORIARTY. Sir, we have over ten million lives covered in a point-of-sale rebate program today. We also, as you heard in my written testimony and oral testimony, we really advocate a zero copay for insulin and other preventive medications. The cost savings associated with adherence is significant.

Mr. RUIZ. OK, I got 20 seconds so let me ask this question directly. What are each one of you willing to give up to make sure that every patient who needs insulin will get insulin? Mr. Mason?

Mr. MASON. We are willing to provide solutions, and we are providing solutions that close the gap to anyone paying out-of-pocket—

Mr. RUIZ. What are you willing to give up?

Mr. MASON. We're willing to give up—we gave up \$108 million last year.

Mr. RUIZ. Mr. Langa, what are you willing to give up?

Mr. LANGA. Last year we invested almost \$18 billion in rebates, discounts, and fees; and we also spent 200—

Mr. RUIZ. But yet the prices are still going up, so the status quo isn't working.

Ms. Tregoning, what are you willing to give up?

Ms. TREGONING. We are willing to contribute to solutions to allow patients to access, and that's why the program that we have allows \$99 at the pharmacy for the insulin—

Mr. RUIZ. Those solutions aren't working if we are seeing doubling, tripling, cost of insulin and our patients are having to ration and not afford their insulin.

Ms. TREGONING [continuing]. And that costs are going down.

Ms. DEGETTE. The gentleman's time has expired.

The Chair now recognizes the gentleman from Virginia, Mr. Griffith, for 5 minutes.

Mr. GRIFFITH. Thank you, Madam Chair.

Mr. Mason, Ms. Tregoning, and Mr. Langa, we have heard that there are numerous fees and discounts in the prescription drug supply chain that are calculated based on insulin prices. According to what I have read, you all have fees with your supply chain partners that are based on a percentage of the list price of insulin. Why are they structured this way?

You are up first, Mr. Mason, let's go. Time is running.

Mr. MASON. We don't—the PBMs kind of own the paper of the contracts and that's what we have to work with.

Mr. GRIFFITH. All right.

Mr. Langa?

Mr. LANGA. It's the current system.

Ms. TREGONING. Agreed, it's the current system.

Mr. GRIFFITH. All right. Have any of your companies tried to negotiate flat fees with your supply chain partners?

Mr. MASON. Yes, we have.

Mr. LANGA. We have tried a variety of different avenues with contracting.

Mr. GRIFFITH. But you have not been successful, why?

Mr. MASON. No, our efforts were pushed away.

Mr. LANGA. I think it's because it's the current system and again in this demand for rebates today.

Mr. GRIFFITH. Ms. Tregoning?

Ms. TREGONING. Yes, again it's the system under which we operate.

Mr. GRIFFITH. So other than just it's the system, what reasons did the other participants in the supply chain provide to justify a fee based on the list price of the medicine rather than a flat fee?

Mr. MASON. It's the current system.

Mr. GRIFFITH. Just the current system, everybody agree with that? All right, because I will move on.

Mr. Moriarty, in the February 6th letter that we sent to CVS Health, we specifically asked CVS Health to list all the contractual terms in your existing contracts that are impacted by the list price of a medicine. CVS Health did not directly answer whether there were any fees charged by CVS that are calculated as a percentage of a list price.

While reviewing the standard contract template commonly utilized between CVS Caremark and a health plan client for several lines of business that the committee received in response to a letter that we sent to CVS Health last August, we saw that there was a section in the template on disclosure of manufacturer fees, that are disclosed that Caremark Part D services may also receive administrative fees from pharmaceutical companies that are based on a percentage of the list price of the medicine. It therefore appears as though CVS Health may use administrative fees that are based on a percentage of the list price of a medicine. This is correct, isn't it?

Mr. MORIARTY. Congressman, over 98 percent of all the fees, rebates that we obtain across our services and 100 percent in Medicare go back to the plan sponsors.

Mr. GRIFFITH. That is not what your contract says. Your contract says you all can charge a one percent fee, an administrative fee based on the price of the medicine. The question that I have is, it doesn't cost your company any more to process a \$4 drug than it does a \$40,000 drug; isn't that correct?

Mr. MORIARTY. It represents the costs associated with that processing, sir.

Mr. GRIFFITH. Well, wouldn't it make more sense from a consumer's standpoint that you came out and be more transparent, but that you came out with a flat fee and worked with these folks over here to come up with a flat fee? Because I understand in Part D on Medicare you are just charging the one percent, but across the board according to your information you sent us you are charging two percent. As a part of the rebate you are getting two percent of that, and I don't know whether you are charging those folks an administrative fee or not, but wouldn't it make more sense just to have a flat fee for doing what you all do?

Mr. MORIARTY. If the flat fee represents what the current net pricing, the lowest pricing it is in the market, yes, we will do that.

Mr. GRIFFITH. You are willing to do a net, even if it costs your company some profit you are willing to do a flat fee?

Mr. MORIARTY. Here's the issue. I think what's been proposed before actually results in not lower costs, actually higher costs. If it results in lower costs, we will implement that.

Mr. GRIFFITH. I mean because one of the problems we have is if you are not in one of the magic companies you are paying the list price and you are not able to afford it, or you are paying the high deductible in order to get there because you haven't reached your deductible yet. And lots of people have opted for these plans, and so the consumer is having to pay that higher list price, they aren't getting all those rebates all the time, and as a result of that their

net price has gone up substantially. That is what we're hearing from our constituents who are having to pay that. It just seems to me that it ought to be something that we all can look at, the whole system needs to be more transparent; and that you all ought to be paid for processing that prescription whether it is a \$4 drug or a \$40,000 drug, you ought to be charged a set standard fee that doesn't have the drug companies coming in here saying, "We are raising our list price," so they can get more.

By the way, how many billions of dollars, or at least hundreds of millions of dollars is represented by that one or two percent?

Mr. MORIARTY. We pass back as I said over 98 percent, and we had disclosed publicly what the retained number is.

Mr. GRIFFITH. What is the dollar number?

Mr. MORIARTY. The total number across is \$300 million.

Mr. GRIFFITH. I yield back.

Ms. DEGETTE. Thank you.

Mr. Kennedy offered an article for the record and, without objection, it shall be entered.

[The article appears at the conclusion of the hearing.]

Ms. DEGETTE. The Chair now recognizes the chairman of the full committee, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you, Madam Chair. I missed a lot of the hearing because we had other hearings, and we were on the floor today with net neutrality. But I just want to say this. All I hear from my constituents, they are just totally disgusted, right. They figure particularly for insulin it has been around a long time, you know, they don't even believe in a market-based system anymore.

I mean, frankly, I believe in a market-based competitive system. I think that, you know, that is what the country is all about. But what they tell me is, just set the price. They will literally say to me, "You in Congress or some Government agency should just set the price and that is it." They just don't believe in a competitive model anymore. So, you know, you keep saying the system, the system, the system doesn't work, well, I guess part of what I would like to know is why this marketplace competitive model doesn't work anymore. What has happened?

So, you know, last week the committee heard from Dr. Lipska, who is a clinician and researcher, and she said, and I quote, "Drug makers make excuses for why prices have gone up. They say it's the fault of PBMs, or wholesalers, or the high deductible insurance plans, but the bottom line is that drug prices are set by drug makers. The list price for insulin has gone up dramatically and that's the price that many patients pay. That is what needs to come down. It's as simple as that." Now, many of my constituents say, very simple, set the price. Have the Government set the price and not have the company set the price. But I mean that is not the competitive model obviously. So let me just start.

Mr. Mason, you set the list price for your insulins, not the PBMs or anyone else in the supply chain. Why are we talking about high drug prices when it is within your power to bring the list prices down? Why don't you just bring the list price down, or do you want us to set it? Because that is what my constituents say. Don't have Mr. Mason set it, you set it. Let the government set it. Why not, if you are not going to do anything?

Mr. MASON. OK, so we—well, we actually buy down everyone in a high-deductible plan down to \$95, so we're doing that today. Everyone who has, on a Lilly insulin at the pharmacy we buy every prescription down to \$95, so we are reducing the list price. We're paying rebates in order to get access and——

Mr. PALLONE. Are you willing to reduce it more?

Mr. MASON. We right now reduce, you know, no matter how much their—you mean, they can use multiple vials, multiple pen packs. We've brought it down to——

Mr. PALLONE. All right. What would be the problem if the Government lists the price and just brings it down and says that is what you have to charge?

Mr. MASON. I mean right now we have—the competition is fierce. I mean our net prices are lower today than——

Mr. PALLONE. So you think competition is working; the marketplace is working.

Mr. MASON. I think it's working, yes. Yes.

Mr. PALLONE. I don't hear that from my constituents.

Mr. Langa, it is unconscionable that these essential drugs have seen dramatic price increases. Why isn't Novo Nordisk reducing its list price? Again, my constituents say force them do it.

Mr. Langa. Well, we do believe in a market-based system. I would also say if we reduced our list price, we would put all of our formulary positions in jeopardy. Just here at the table, these three PBMs represent 220 million covered lives, and for us the risk that——

Mr. PALLONE. So you are going to blame the PBMs again.

Mr. Langa. It's not the blame. We don't want to put those lives at risk, but we are willing to——

Mr. PALLONE. All right, so then let's get rid of the PBMs and we will just set the price, the Government will set the price and you don't have to worry about the PBMs. What do you think?

Mr. Langa. It's not what we believe in. We take a market-based approach and it is competitive.

Mr. PALLONE. I agree with you, but nobody thinks it is competitive anymore.

Mr. Langa. So if you look at our rebates, the average rebate for Novo Nordisk in 2014 was 48 percent. The average rebate just 4 years later in 2018 was 68 percent. That's a 40 percent increase. We spent up to \$18 billion last year in rebates, discounts, and fees to provide formulary access, so.

Mr. PALLONE. All right, let me—I think you are just passing it on to the PBMs.

Ms. Tregoning, same question is people being forced to ration their insulin because they can't afford it. What is stopping Sanofi from lowering its list price? Why don't we just set the price ourselves?

Ms. TREGONING. Congressman, unfortunately, under the current system simply lowering list price as I believe some of the witnesses last week attested to might not help patients and actually could cause some patients, who are on their formularies where we've secured position with rebates, to lose access. If we could get——

Mr. PALLONE. But if we set the price there would be no PBMs anymore.

Ms. TREGONING. Congressman, I believe that the market-based system is very important for continued innovations. We don't—

Mr. PALLONE. I agree, but you guys have got to convince us that it is working and that the, you know, the problem that we have is we always end up having to interfere with the market when it becomes monopolistic, when it is not working, and my constituents say it is not working. "What are you doing, Pallone? It is not working."

Ms. TREGONING. Congressman, competition is working. The net prices are coming down. The issue we have is that the results of that negotiation are not finding their way to patients, and that's the issue at hand. We at Sanofi are working, where patients are exposed to those high list costs, we are effectively de facto having a lower list price and covering through copay assistance or VALy you Savings Programs. But we don't control the out-of-pocket costs.

Mr. PALLONE. I mean the problem is, Madam Chair, I know my time is up, but everybody just blames, you know, the PBMs blame the companies, the companies blame the PBMs, and our constituents say they are all no good, just get rid of the system. I am reluctant to do that because I believe in a market-based system. But this is, you know, this is what I hear. Thank you.

Ms. DEGETTE. Thank you, Mr. Chairman.

The Chair now recognizes Mrs. Brooks from Indiana, for 5 minutes.

Mrs. BROOKS. Thank you, Madam Chairwoman.

I think everyone is focused and the answers all seem to be focused on the system which I think we all are acknowledging and are very frustrated. It seems to be very broken. In the February 6th letter that we sent to the manufacturers we heard it is becoming increasingly common for insurers and PBMs to only offer one insulin manufacturers' line on their formularies.

I want to ask some questions about formularies and because it sounds like everyone in this finger pointing is having to do with formularies. And so, I am curious, why are, and not, you know, being involved in, but we are all learning a lot more about this system, why is it that you might have one insulin on a formulary? Why wouldn't you want all of them to be on your formularies?

I also have a question because if you are, say, an employee's daughter or son and you are used to one insulin then the company switches their insurance program and then that child has to go to different insulin, why would we not offer as many options as possible?

I will start with you, Dr. Dutta. If you could, you know, why do we make this change and then the rebates get in the middle of it and the discounts, and can you just help us? The system seems really broken and it sounds like that is part of it.

Dr. DUTTA. Thank you for the question. The first assessment is purely clinical. It is about whether a product is unique or if there are therapeutic alternatives. So when you have a unique product, price is high. It's put on our formulary, there is no competition. Then as manufacturers produce more products that are therapeutically equivalent, in the case of insulins rapid-acting insulins, long-acting insulins, in a category then there's an opportunity when they're equivalent to negotiate price down off of list price. However,

to your specific question, if there's a patient that requires a medication that is not our preferred product or not formulary, we offer a process for the patient and their doctor to request and provide rationale for their product. If there's a good reason like an allergy or something like that, then they would be allowed to have that product.

Mrs. BROOKS. Thank you.

Ms. Bricker, what would happen in the market for you to stop, for you, not just your company, but all of the PBMs here, what would happen if you stopped excluding certain insulin products from the formularies, if you allowed all of them in the different categories of insulins as I understand, if you allowed all of them to compete and be on each of your formularies?

Ms. BRICKER. Yes, thank you for the question. We don't have one formulary. We have many, many, many formularies. The formulary that provides the greatest savings for our clients actually limits through exclusivity or exclusive placement insulin options. We do that because we're able to secure the deepest discount from the manufacturer once we award that placement. And so, they're offering discount in exchange for market share and in exchange for access.

But to your point, we have other options and we believe that choice to our plans is critical and they absolutely can select formularies that have all insulin on the formulary.

Mrs. BROOKS. What if we removed exclusivity from formularies?

Ms. BRICKER. Prices would go up.

Mrs. BROOKS. Why do you believe prices would go up? Mr. Moriarty, why would prices go up if all of the companies were able to be a part of your formulary? Mr. Moriarty?

Mr. MORIARTY. Because the drug companies would not offer the discounts that currently exist in the system.

Mrs. BROOKS. And so, if we were to remove all exclusivity from formularies, Mr. Mason?

Mr. MASON. You know, our rebates went up during the period were removed from kind of dual access to exclusive formularies. That's what caused the list prices to go up.

Mrs. BROOKS. Mr. Langa?

Mr. LANGA. Our rebates have been competitive for years. Year over, year over year they're competitive. We believe in choice, choice for the physician, and choice for the patient. Someone that—a physician should be able to use their clinical experience to make decisions, not a formulary.

Mrs. BROOKS. What if we got rid of rebates and discounts, Ms. Tregoning?

Ms. TREGONING. We would support moving to a system in which you had fixed fees for PBMs and that we removed rebates. As long as patient access and affordability could be guaranteed, we would be more than happy to move to that system.

Mrs. BROOKS. Do you think if we had systems like that you all would lower your insulin prices that would be offered?

Ms. TREGONING. If we could be assured that patient access and affordability would be maintained, we would certainly be willing to lower our list prices, if we moved away from a rebate system.

Mrs. BROOKS. Mr. Langa?

Mr. LANGA. Yes, we support the rebate rule and we also support that if as long as there's access and affordability we are open to that option.

Mrs. BROOKS. Mr. Mason?

Mr. MASON. Same answer.

Mrs. BROOKS. Thank you. I yield back.

Ms. DEGETTE. The Chair now recognizes the gentlelady from New Hampshire, Ms. Kuster, for 5 minutes.

Ms. KUSTER. Thank you.

Thank you very much for your testimony today and as we unravel this whole process of rebates and volume discounts the high cost that patients and families are facing for insulin. In New Hampshire we have 121,000 Granite Staters, just give or take ten percent of our population, actually, have either type 1 or type 2 diabetes. These are the people that I have in mind, the families that we have been hearing from.

But I want to understand, the frustration that the diabetic Americans come not just from the dramatic increases in the out-of-pocket costs, but the mind-numbing complexity of how the drugs are priced and a belief that insulin manufacturers and pharmacy benefit managers may have lost focus on who they are truly meant to be working for, the patient. So that is really where we are coming from is to try to understand as we unravel this.

You have heard some of the ideas here, which I would imagine would be a dramatic change in the way you do business on certainly from the conversations I have had with the PBMs, but also from the manufacturers' point of view. I mean, I don't think anyone really comes to this with totally clean hands because you are chasing the profits of the quarterly earnings as well as anyone else.

I think part of what is difficult for us to understand is these are medicines that have been around for a long, long, long time without a great deal of innovation, without a change in the chemistry and the medication itself. Maybe there has been a change I understand in the delivery mechanism, you know, maybe there is a medical device change in having a longer lasting impact on patients, and certainly for patient convenience and patient health that is important.

But we are trying to get to the bottom of why this has gone up so much. It is one thing for us to consider that in a field of medicine that has dramatic new innovations and the R&D costs, but it is all the more complex for us to sort that out with something like insulin.

I want to get at two areas, if I could. Just, Mr. Mason, what efforts would you recommend to Congress to improve price transparency for patients? You obviously have taken a stand on getting rid of rebates or those types of things, but what is it that should be happening in terms of the patient understanding the pricing?

Mr. MASON. We're open for transparency to help patients. We think the biggest issue that we're hearing right now—we want the same thing. We're not defending the system, we're just explaining the system up here. We want reform. We want, you know, anything that provides better access to patients. The heart of what we're hearing from patients is those with high-deductible plans, about half of those high-deductible plans will take the rebates that are

given to them and they use those to afford chronic, or affordable care for those with chronic disease. About half of them decide to actually put that back and actually lower premiums for the general population.

So what we hear and what you're probably hearing is for those individuals who are in those high-deductible plans where that employer has decided to say, "I'm going to pick the plan design that gives me lower premiums," because they're prioritizing that. They're making that conscious plan decision and that leaves individuals with chronic medication paying this price. That is a gap in the system right now that is leading to what we're hearing the most from diabetes patients.

Now we're providing now a stop-gap measure to buy all those people down to \$95, but that's a short-term fix. Long-term fixes should really be focused on what can we do with these high-deductible plans so that they have affordable coverage from day one and that decision is universal.

Ms. KUSTER. So you would agree that there is a discount for volume purchasing, and are you saying they fall outside—and I can ask Ms. Bricker to explain this.

But—well, let me go to you, Ms. Bricker. What he is saying, how do we get to transparency for the patient, and how do we get all the patients to benefit from a mechanism that makes sense to me that you have described which is a volume discount, essentially? That is what the rebates are.

Ms. BRICKER. A couple of things, if I may, so believe strongly in having real-time benefit check at the time of prescribing that the physician has at his or her fingertips, what product is covered under the formulary, and what it will cost the patient, absolutely critical to ensuring that there isn't friction at the counter. Transparency, also, to plan sponsors so that they fully understand the value that we've negotiated for them by way of rebates and discounts.

And so of course we've got to continue to do more. We've, as mentioned previously, announced a program for \$25 insulin for all of our commercial patients. But clearly where we're still faced with challenges in the Part D benefit and we are absolutely in support of continuing to modernize that benefit such that patients, you know, have caps and don't have, aren't exposed to these high list prices, essentially.

Ms. KUSTER. My time is up, but thank you.

Ms. DEGETTE. Thank you. The gentleman from West Virginia is now recognized for 5 minutes.

Mr. MCKINLEY. Thank you, Madam Chairman. I apologize. I have been back at two other committee meetings going on, so I have missed some of your—but I heard enough of it.

Mr. Langa, I probably would focus most of my remarks towards you on this. I was here, so just begin, for my records the only thing that we have some information that we were—a vial of insulin in '67 cost a dollar. If just the CPI went up \$17, but yet your NovoLog is now with a list price of 237, not \$17.

So many times, when we have our meetings back in the district in our roundtable discussions they talk about how people in West Virginia, probably no different than around the country, having

three and four hundred dollars a month. I just talked with that fellow this morning, he said he just wrote a check for a thousand dollars for his insulin in excess of his insurance.

What I was hearing not only similar dollar increases like this, but I was hearing all of you say it was caused by innovation, in part by innovation. I am curious what kind of innovation have we implemented over the last few years that would cause such a drastic increase in the price of insulin, the innovation part of it? Because let me just, I am a strong, strong supporter of innovation, so help me out a little bit. Why is innovation causing the increase in price?

Mr. LANGA. Sure, so innovation is very important to us as an organization, we're an innovator company. I would tell you that what's most important, and I think it was mentioned earlier, is that we keep the patient in mind. Because even that word "incremental," it's not incremental to patients.

So when you think about going from 4 to 6 injections a day to one, if you think about being able to take a mealtime insulin at or right after you eat versus an hour to an hour and a half before, if you think about basal insulin or long-acting products today that give you the support of hypoglycemia, maybe the best way I could describe it is: we have patients that want to work for Novo Nordisk because of the mission that we're on to defeat diabetes, and we have these patients sometimes speak at our company meetings.

Mr. MCKINLEY. I am just trying to understand the innovation part of it.

Mr. LANGA. But I am going to, I think, get to it.

Mr. MCKINLEY. Please get to it because we have run out of—I don't need someone to filibuster here on me.

Mr. LANGA. It's not filibustering, it's this individual talk about what he lives with; night terror. Night terror is something called low hypoglycemia at night and actually makes him do things that are out of what he normally does. And because he got on a product called Tresiba that reduces hypoglycemia 40 percent—

Mr. MCKINLEY. You are saying, you are saying the innovation that—

Mr. LANGA [continuing]. He has not had a night tremor since.

Mr. MCKINLEY. I am saying if—were prior to having the innovation that prices were lower, now they are skyrocketing up to 237. Can we just stop the innovation? If it worked before, why in the last five years through innovation we have gone from 17 or \$20 up? I don't want to go there, because as an engineer I believe very much in research and to do that, but if we are driving the price up—innovation is supposed to drive the price down, not up.

I am really troubled with it. But I think it is—

Mr. LANGA. Innovation is for today, and tomorrow I think it's important because we're innovating for the future and the future of people living with diabetes. So it's a partnership with MIT. It's our partnerships with the University of California San Francisco.

Mr. MCKINLEY. I want to respond back to why that in the past, until the last few years that I am sure you were innovating back in the '70s and '80s, the innovation and it wasn't skyrocketing like it is right now. So it is just counterintuitive that why innovation is driving the price up now in the last few years.

Let me go back to the list prices because I am not going to—we are going to run out of time. But I don't understand that—I come from the construction industry, but also in life I need to see some examples of why we have these list prices set up for discounts I have heard you talk about. If we don't have rising list prices for cars and appliances and construction material, why is it that pharmaceuticals are jazzing up the list price so they can offer discounts? Why is that unique to the pharmaceutical field?

Mr. LANGA. Again, I know you've heard a lot about this today, but it is about these misaligned incentives in the system. The higher the rebate—excuse me. The higher the list price, the higher the rebate.

Mr. MCKINLEY. Yes.

Mr. LANGA. The rebates are used within the system. And that is—and again, and those rebates don't get passed through to the people living with diabetes and that is there that lies the challenge.

Mr. MCKINLEY. Should we eliminate or discourage the rebates?

Mr. LANGA. Well, certainly we're supportive of the rebate rule, and we're supportive of the pass-through of those rebates to benefit patients, and we think that would be something that would be healthy for patients.

Mr. MCKINLEY. OK, I have run out of time. I am sorry. I yield back.

Ms. DEGETTE. The Chair now recognizes the gentlelady from Florida for 5 minutes.

Ms. CASTOR. Well, thank you, Chair DeGette for holding this hearing to tackle the skyrocketing insulin prices.

I recently met with a family from back home in Tampa. Nine-year-old Brooke and her father Todd explained to me how she was diagnosed when she was three days old in the hospital and how they have struggled with her diabetes since then. But it is not just—the big struggle hasn't really been on the health side. It has been with affording insulin and drugs. They have had to change their lifestyle a little bit and Todd told me at one point they had run out of insulin two weeks before the end of the month and had to borrow a vial from an adult friend of ours who was using Humalog and had numerous vials stockpiled.

That is how, he said, "That is how we do it now. We tell our endocrinologist that we use more insulin than we need in a month, so she writes prescriptions for slightly more than we use. Since the vials are good for two years, we have extra in case anything happens. At the end of the day, we count ourselves blessed that both my wife and I work, and our insurance sufficiently helps pay for all of Brooke's type 1 diabetes supplies, but the beginning of the year is still very difficult until we pay our deductibles. We choose to pay more for our insurance out-of-pocket to make those deductibles." But he says, "I cannot fathom how a family can choose to limit or ration insulin for their children. The system needs to be fixed."

Then I asked Brooke, I said, "What would you as a 9-year-old having to deal with this, what would you want me to ask?" She says, "Why do we have laws that protect kids' safety like bike helmets, seatbelts, and indoor smoking bans, but not laws that would allow them to get the medicines they need to stay alive?"

So this, things have got to change. So let's start with manufacturers' list prices and how we get them under control. It seems to be that just about everyone in the supply chain except the patient is benefiting from increasing list prices.

Mr. Mason, if rebates and fees tied to list price were to be restricted or eliminated, do we have any guarantee from Eli Lilly that prices would go down and patients would pay less?

Mr. MASON. We would definitely consider it.

Ms. CASTOR. Mr. Langa?

Mr. LANGA. Yes. We would consider that, yes.

Ms. CASTOR. Is there a guarantee?

Mr. LANGA. Well, what's important to us again is that the majority of patients can have access at affordable pricing and as long as there was that in place then, yes, we would consider that.

Ms. CASTOR. Ms. Tregoning?

Ms. TREGONING. Yes, as long as we can ensure patient access and affordability in formularies then we would certainly lower list price with the elimination of rebates.

Ms. CASTOR. OK. There is another hitch in the system here and that is kind of the gaming of charitable contributions. It has been reported that some manufacturers use the Patient Assistance Programs to reduce their own tax burden. That by donating drugs to these Patient Assistance Programs, the company is able to deduct the value of the donated drugs from its taxes.

In 2015, I understand Lilly donated 408 million worth of drugs to the Lilly Cares Foundation. Mr. Mason, should manufacturers be able to benefit financially from the Patient Assistance Programs?

Mr. MASON. We do it only to help patients. We don't want anyone not to afford—

Ms. CASTOR. But boy, that is a big—408 million, then I would think we would see some commensurate reduction of the list price that would be tied to that.

Mr. MASON. Our net prices are going down, and then what you're not seeing is we spent \$108 million last year on savings offers that helped 525,000 people. Those aren't a tax write-off. Those are—

Ms. CASTOR. I think there is an issue here though with these kinds of charitable contributions. You seem to be benefiting on both sides and patients aren't.

So turning to the PBMs, Ms. Bricker, if fees paid to PBMs and wholesalers are standardized and entirely delinked from the list price, what impact would it have on what the patient ultimately pays?

Ms. BRICKER. Over 50 percent of our clients receive all fees that are collected from manufacturers and 95 percent of all fees and discounts and rebates are passed on to our plan sponsors. And so, ultimately when you delink the fee from the list price, there really is nothing that prevents the manufacturer from continuing to increase the price.

Ms. CASTOR. So, Mr. Dutta, the mission of PBMs is to get the lowest price possible for drugs for their clients, but that clearly isn't happening. How can we change the system to better align out-of-pocket patient cost to negotiate a net cost instead of the list prices?

Dr. DUTTA. Well, 76 percent of our members today either pay zero-dollar copay or most commonly a flat copay of \$35. And for that other percentage that you're asking about that are on a coinsurance or a high-deductible plan we advocate for point-of-sale rebates as well as preventive drug lists such that insulins would not apply to the deductible.

Ms. CASTOR. I yield back my time, thank you.

Ms. DEGETTE. Thank you. The Chair now recognizes Mr. Mullin for 5 minutes.

Mr. MULLIN. Thank you, Madam Chair, and thanks for holding this meeting. It is not too often we get together and actually agree on issues, but we are all talking about the same thing; and we are all scratching our head trying to figure out how we got to this point.

Real quickly, I want to go back to what was just asked about YOUR tax advantage for taking the rebates. Is there a tax advantage for YOUR companies for those rebates, yes or no?

Mr. MASON. No.

Mr. MULLIN. No.

Mr. LANGA. No.

Ms. TREGONING. No.

Mr. MULLIN. Well, what about the charitable contributions? Is that not a tax advantage?

Mr. MASON. We only give insulin and what people use.

Mr. MULLIN. Well, because if it is at \$300, and I am just using generic numbers, if the list price is 300, you put your rebates in and you get it all the way down to 100, who absorbs those rebates?

Mr. MASON. That's not why we're doing it. We're doing it for—

Mr. MULLIN. No, who absorbs those rebates?

Mr. MASON. Those—

Mr. MULLIN. Who absorbs those rebates? Do you guys absorb those rebates? If you are giving the rebates and the list price is at \$300, you are getting it to \$100, who absorbs those rebates?

Ms. TREGONING. The rebates go to the PBMs with whom—

Mr. MULLIN. It doesn't go to the patient though, right?

Ms. TREGONING. That's based on the—that's the concern that we have.

Mr. MULLIN. Do you write that off as a charitable contribution?

Ms. TREGONING. That's different than a charitable contribution. The free drug program which are run through Patient Assistance Programs—

Mr. MULLIN. OK.

Ms. TREGONING [continuing]. That's different. That's providing free drug to patients below a certain income threshold. That's separate from rebate—

Mr. MULLIN. You know what Mr. Griffith asked back here in the back, the innovation—no, I am sorry—McKinley asked about the innovation. When you are talking about the innovation side of things, are you using insulin today to help pay for future drugs? Is that the innovation that you guys are using for research? Does the price of insulin help offset the cost of research for future drugs?

Ms. TREGONING. Revenues from all of our business, in part, go back to fund research and development across all areas. For diabe-

tes in the United States, I would point out our revenues have gone down.

Mr. MULLIN. But I can understand price. A lot of you guys come in and you talk to me in my office and you say, "Look, the price of the drug is so we can recoup our cost to develop it. That was the cost so that is why it is set at where it is because we are trying to recoup the cost of it." I totally get that. You have got to recoup the cost especially when you start having patents that are going to run out and you need to recoup your costs in time.

But the cost is already recouped in this, so you are using insulin today, the cost of insulin today to pay for future drugs that are outside of insulin; is that correct?

Ms. TREGONING. We continue to invest in research—

Mr. MULLIN. That is why you are seeing it go up so much?

Ms. TREGONING. No, because our revenues from diabetes are going down. The net prices are going down. Our revenues from—

Mr. MULLIN. But you don't have any costs associated with it because it has already been developed. It has already been paid for.

Ms. TREGONING. But again, the revenues for Sanofi's diabetes business in the U.S.—

Mr. MULLIN. OK.

Ms. TREGONING [continuing]. Have gone down by half over the last four years because net prices have gone down so dramatically.

Mr. MULLIN. I have some quick questions I need to get to. If a patient qualifies for YOUR programs, how much does it cost? How much does their insulin cost at that point?

Mr. LANGA. Patient assistance is free.

Ms. TREGONING. For copay assistance they'll pay no more than a \$10 copay.

Mr. MULLIN. OK.

Ms. TREGONING. But if they qualify for the charitable then it is free drug.

Mr. MULLIN. OK.

Mr. MASON. Patient assistance is free.

Mr. MULLIN. Is free.

Ms. Bricker, with the Express Scripts you guys came up with no more than a \$25 charge to customers. You just rolled that out recently, right? How long did it take you to develop that?

Ms. BRICKER. We've been working on it for a few months.

Mr. MULLIN. For a few months. Have the companies here on the panel, have they agreed to participate in that with you?

Ms. BRICKER. Yes, they have.

Mr. MULLIN. It took you two months to come up with that. How are you guys able to offer that?

Ms. BRICKER. In collaboration with the manufacturers as well as in collaboration with the plan sponsors.

Mr. MULLIN. When a patient qualifies for YOUR programs, how long do they typically stay on those Patient Assistance Programs? Either one.

Mr. LANGA. It varies. It varies, really, by patient program. So they have renewal periods, but it could be 1 year, 3 years.

Mr. MULLIN. Do you know what average the patient stays on the program?

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Mr. LANGA. I'd have to get back to you on the average. I don't know what that is.

Ms. TREGONING. I don't have that information.

Mr. MULLIN. Mason?

Mr. MASON. Our separate foundation does that, so we don't have that data.

Mr. MULLIN. OK, I will yield back.

Thank you so much for your time.

Ms. DEGETTE. Thank you. The Chair now recognizes the gentleman from New York, Congressman Tonko, 5 minutes.

Mr. TONKO. Thank you, Madam Chairwoman.

I would like to begin by asking our panel a number of simple yes or no questions. During our hearing last week, patient advocate Gail DeVore testified that against her doctor's orders she had rationed and diluted a bottle of insulin because she couldn't afford to pay the \$346.99 it cost her per month. Are you aware of stories like Gail's, and we will start with you, Mr. Mason, and go across, but yes or no, are you aware?

Mr. MASON. Yes.

Mr. LANGA. Yes, we are.

Ms. TREGONING. Yes, we're aware.

Mr. MORIARTY. Yes.

Ms. BRICKER. Yes.

Dr. DUTTA. Yes.

Mr. TONKO. Have any of you personally ever had to ration a vial of insulin?

Mr. MASON. I have not.

Mr. LANGA. I have not personally.

Ms. TREGONING. No, I have not.

Mr. MORIARTY. I have not.

Ms. BRICKER. I have not.

Dr. DUTTA. No, and no one should.

Mr. TONKO. Similarly, I hear stories from my constituents frequently about the struggle to afford lifesaving medications including having to make tough choices about putting food on the table or simply buying medication. Have any of you ever personally had to choose between feeding your family or buying a life-sustaining medication?

Why don't we start with you, Dr. Dutta, and go the opposite way?

Dr. DUTTA. No, and no American should.

Ms. BRICKER. No, I have not.

Mr. MORIARTY. I have not.

Ms. TREGONING. No, I have not, and agree no one should.

Mr. LANGA. I have not and no one should.

Mr. MASON. I have not and no one should.

Mr. TONKO. In a broader sense, have any of you ever struggled to afford a medication that was recommended to you by your doctor?

Mr. MASON. I have not.

Mr. LANGA. There once was a time when one of my children had to be on a growth hormone product and we were not able to get reimbursement. At that time, it was going to be several thousand

dollars and that was going to be a challenge for us. So yes, there was a time in my life.

Mr. TONKO. Thank you.

Ms. TREGONING. I'm fortunate not to have faced that situation.

Mr. MORIARTY. I have not.

Ms. BRICKER. I have not personally, but yes, my family members have struggled.

Dr. DUTTA. No, I have not and no one should.

Mr. TONKO. Well, I thank you for your candor. I want to be clear that I am not asking these questions as a gotcha moment, but as a reminder that we need to approach this issue with empathy and compassion. We never know what the person next to us might be going through. These stories we have all heard and are sharing today are from real people.

Modern medicines like insulin save lives, but when we dangle these life-sustaining medications just out of reach from those who need them, we are engaging in a most cruel form of torture. According to Dr. Lipska's testimony last week, one in four individuals reported using less insulin than prescribed over the past year specifically because of cost. Let's put ourselves in their shoes for the day.

We can get bogged down here in Washington with the blame game and talk about esoteric issues like rebates and list prices and Patient Assistance Programs, but the reality is that when I go this weekend back to my hometown to Amsterdam, New York, there will be people in my community that are in the hospital putting their lives at risk, because they are so desperate for this medication that they are priced out of that they deliberately let their blood sugar crash just so they can get free samples of insulin on their way out of the door. Regardless of where you pin the blame, the system as it exists now is horrendously broken; and the companies represented at the witness table are benefiting while patients across the country are losing. That is unacceptable and we need answers.

Last week, in testimony before the committee we heard from the Endocrine Society that in 2017 expenditures for insulin in the United States reached some \$15 billion. They also told us that three of the top ten medication costs were for a type of insulin. Where is all this money going?

Let's start with you, Mr. Mason.

Mr. MASON. Our net prices are going down. Why we hear so much of why people can't afford their insulin today, it's those individuals in about half the high-deductible plans that don't benefit from the rebates and have high out-of-pocket costs because the rebates are being used to buy down the premiums.

Mr. TONKO. Do those net prices need to go down further?

Mr. MASON. Our net prices are going down.

Mr. TONKO. No, you said they are, but do they need to go down further? In order for people to—we hear about CEOs getting an increase in their salary and we—tell us, well, the response is our net prices are going down. Do they need to go down further or do we need to take from the CEO?

Mr. MASON. All I'm saying is our net prices are going down. The price that plans pay, payers pay to get insulin is going down, but

those costs are not being used to help people who have diabetes in about half of the high-deductible plans. Those rebates are used in order to buy down premiums for the general population leaving those with chronic medications like insulin exposed to a deductible. That's what we're hearing. That's the point that we need to focus on solutions. That's the gap in the current system. The current system's not working. We agree a hundred percent. That is the heart of the issue.

Mr. TONKO. Well, I see my time is up, I will yield back. But again a crisis that we need to resolve as soon as possible, quickly here. Thank you and I yield back.

Ms. DEGETTE. The Chair now recognizes the gentlelady from New York, Ms. Clarke, for 5 minutes.

Ms. CLARKE. Thank you very much, Madam Chair, and I thank our ranking member. This is a very important hearing today and I wanted to ask a couple of questions.

We have heard a number of examples of the dramatic rise of insulin prices this afternoon and I am still not clear on the flow chart. You know, we have heard a whole lot of different things about net pricing, list pricing, and that net pricing is going down.

Is that what you are saying, Mr. Mason? OK, now is that subject to ebbs and flows? In other words, if you are saying that price is going down as we sit here, is there a point where that price gets settled at a lower price or is there the possibility that it rises again? Is it like oil?

Mr. MASON. No, it's not like oil. I mean this has been pretty flat over the last 10 years. We can provide the, I think we provided the data as part of our written testimony.

Ms. CLARKE. Well, how is it then if they are going down over the past 10 years that it is still unaffordable? That is the flow chart that I am talking about. If you are going down—first of all, it spiked for some strange reason, I guess the change in the system or the, you know, modernization of the system that included this rebate, you know, shenanigan, because that is what it is at the end of the day, if you have a 100-year-old product that increased in value because all of these other dynamics got involved and, you know, it is the same product.

Can you give me a sense of what happens when you produce this product, what the cost is, and then how it gets to the point where the average American can't afford, who needs it, can't afford to access it? That is the crux of this for, I think, the listening public. Because we have talked about a lot of terms of art here, but Americans need to know how you got to where you are given what we know. Can you explain? Can you explain, or is there anyone on the panel that can explain it in layperson's terms?

Ms. TREGONING. Congresswoman, first, the insulins of today are very different than the insulins of the past, so I think that's also very important to keep in mind. That the insulins today—

Ms. CLARKE. We understand that.

Ms. TREGONING. In terms of the list versus net prices, the net prices have been going down steadily. We talked about our insulins. Our list price has gone down 25 percent over the last five years, or since 2012, and that is expected to continue. The issue here is that the savings—

Ms. CLARKE. What precipitated that?

Ms. TREGONING. It's additional competition and rebating—

Ms. CLARKE. Are you sure it wasn't the outcry of the public that could no longer afford it that are watering down their insulin?

Ms. TREGONING. Unfortunately, Congresswoman, the lower net prices are not finding their way to patients, exactly to your point. That the rebates that exist in the system that gap between the list and the net prices is being used to subsidize other parts of the system and so, unfortunately, patients—

Ms. CLARKE. So the system became far more complex over time. Is that what you are—

Ms. TREGONING. I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient.

Ms. CLARKE. If we extract rebates from the system, what happens?

Ms. TREGONING. If we moved to a system of fixed fee, we support the rebate rule then we would be able to lower our list prices, but we would need to ensure that the formulary position—

Ms. CLARKE. No. I just want to know if we removed the rebates.

Ms. BRICKER, I think you had—

Ms. BRICKER. If you remove the rebates, the discounts, there is no one that's advocating then for the patient and the plan sponsor to drive discounts and affordability. The rebates are discounts. They sound mysterious. It's just a discount and it's a volume discount.

Ms. CLARKE. Right.

Ms. BRICKER. And so PBMs serve a critical function in ensuring affordability. Are there people that slip through the cracks? Absolutely, and we're absolutely committed to figuring out how to serve each and every patient. But I would caution, doing away with rebates will only increase costs.

Ms. CLARKE. OK.

Ms. TREGONING. We support having rebates pass through to patients, pass through to the patients who use the drugs upon which the rebates have been negotiated. That's—

Ms. CLARKE. This is a circular issue, because you want that passed on to the patient.

Mr. LANGA. Yes.

Ms. CLARKE. So that you can continue to push up the price.

Ms. TREGONING. We don't receive list price. We receive the net price. We don't receive the list price.

Ms. CLARKE. You don't receive the list price.

Ms. TREGONING. No. The price that is paid to manufacturers is ultimately the net price.

Ms. CLARKE. Right.

Ms. TREGONING. So the rebates now are being used to offset other costs in the system. What Sanofi would advocate for is ensuring that those rebates are provided to patients who are using the drugs; upon which those rebates are negotiated to lower their out-of-pocket costs.

Ms. CLARKE. Are you saying that the PBMs' demand for increased rebates is the reason you are forced to keep raising your list prices?

Ms. TREGONING. It is one component of how we consider and at Sanofi we have limited our list price increases. But one component of that decisionmaking is the dynamics of the supply chain.

Ms. CLARKE. What are the other components?

Ms. TREGONING. The other components include the need to continue to invest in R&D and the competitive environment.

Ms. CLARKE. I yield back. I think it is more P&G. That is profit and greed. I yield back, Madam Chair.

Ms. DEGETTE. The Chair now recognizes the gentleman from Maryland, Mr. Sarbanes, for 5 minutes.

Mr. SARBANES. Thank you.

Is the rebate, Ms. Bricker, is the rebate system transparent right now would you say?

Ms. BRICKER. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the Government, health plans, what we negotiate for them is transparent to them.

Mr. SARBANES. So we can track the list price, then we can see the rebate, then we can see the net price, then we can see the savings that you pass along to the consumer; that is all completely transparent to the public?

Ms. BRICKER. It's not transparent to the public unless they are our patient.

Mr. SARBANES. Should it be?

Ms. BRICKER. We don't believe so.

Mr. SARBANES. Should it be a trade secret, is that the problem, like proprietary—

Ms. BRICKER. The reason I'm able to get the discounts that I can from the manufacturer is because it's confidential.

Mr. SARBANES. It is a secret.

Ms. BRICKER. Because it's confidential.

Mr. SARBANES. Yes, because it is a secret. What about if we made it completely transparent? Who would be for that?

Ms. TREGONING. We would support transparency along the entire chain. That's the important thing is if we have transparency all along from the list price all the way through to patients.

Mr. SARBANES. Do you all support that?

Ms. BRICKER. Absolutely not, but—

Mr. SARBANES. No, you can't, because then it will end up hurting the consumer.

Ms. BRICKER. It will hurt the consumer.

Mr. SARBANES. Yes, it will hurt the consumer to have transparency, you know?

Ms. BRICKER. It will hurt the consumer, Congressman, because—

Mr. SARBANES. I don't buy it.

Ms. BRICKER [continuing]. Prices will be held high.

Mr. SARBANES. I am not buying it. I think a system has been built that allows for gaming to go on and you have all got your talking points.

Ms. Tregoning, you have said you want to guarantee patient access and affordability at least ten times, which is great, but there is a collaboration going on here. I know there is this going on too, but the system is working for both of you at the expense of the patient.

Now I reserve most of my frustration for the moment in this setting for the PBMs, because I think the lack of transparency is allowing for a lot of manipulation. I think the rebate system is totally screwed up, that without transparency there is opportunity for a lot of hocus-pocus to go on with the rebates. Because the list price ends up being unreal in certain ways except to the extent that it leaves certain patients holding the bag, then the rebate is negotiated, but we don't know exactly what happens when the rebate is exchanged in terms of who ultimately benefits from that.

I think we need more transparency and I do not buy the argument that the patient is going to be worse off, the consumer is going to be worse off if we have absolute transparency. I think just to get the lobbyists in the room to shudder a little bit, I think the PBMs should be utilities or converted to nonprofits or something. I know when you started out, I understand what the mission was originally with the PBMs. It is a complicated industry. You need an intermediary to assemble all the information on both sides, to weigh in, to assemble the bargaining position so that you can get the best price, and in the early days that was a good argument.

But now things have gotten out of control. You are too big, and the lack of transparency allows you to manipulate the system at the expense of the patient. I don't buy the argument that the patient and consumer is going to get hurt if we have absolute transparency. If we can't get it from a for-profit entity like the PBM, then we ought to look at other ways of doing it, including having the Government get into this space and compete in providing that important function. With that I will yield back my time.

Ms. DEGETTE. The Chair now recognizes the gentlelady from Illinois, Ms. Schakowsky, for 5 minutes.

Ms. SCHAKOWSKY. Thank you, Madam Chair, for holding this hearing.

I don't know if I have any questions at all, but I want to tell you something. In the 2018 election, the number one concern of Americans, the high cost of prescription drugs. We have the names of people who have died because they couldn't get their insulin. A young man who was trying to control it himself after going off his parents' policy, dead. We know that a huge number of people are not taking the insulin that they need because they can't afford it. So then they get sick, they get sicker, and maybe they die because of it. I don't know how you people sleep at night.

Between 1996 and now, when you have Eli Lilly from \$21 a vial to \$275, you heard Mr. McKinley—am I saying that right—who went through all that, interesting by the way. So for Eli Lilly it is now \$275. For Sanofi it is \$270. For Novo Nordisk it is \$280. Curiously close in price and way too high. I want to tell you something. That will not stand in this Congress. I heard Ms. Brooks say the system is broken and I think on both sides of the aisle there is a commitment. We have even heard the President of the United States talk about price gouging. Yes, we need transparency. I have

a strong transparency bill that is going to hold you guys accountable and make you notify how you justify raising those prices. You talked about another—Mr. Langa, you talked about another drug that you are developing and that somehow that is an excuse because it helps diabetics and that is the research and development that you do. You are in trouble. And the lobbyists out here, or maybe that is you, need to understand that this is a commitment on the part of the Congress to get drug prices, particularly life-saving, life necessities, to get those prices under control. If you think you can, you know, just out-talk us without any transparency, without any accountability, I just want you to know your days are numbered.

You know, when Mr. Azar became the Secretary of Health and Human Services, I wanted to remind him that he came from Eli Lilly at the very time that those insulin prices went through the roof, and we are seeing that on drugs that have been like yours on the market for decades. If you want to try and explain—I totally agree, isn't that a good thing that now people may be able to take one vial and not have to shoot up all the time because, you know, and the delivery system. But we had no clue if that means that you can raise those prices a thousand percent.

And you think you can get away with that kind of secrecy or just blaming the PBMs. I am not holding them unaccountable here, we need to do that. But don't excuse yourselves from this and don't tell us about the wonderful charity prices that you give and then you do get tax breaks, I am assuming—contradict me if I am wrong—when you give charity care to people. I believe that that is a tax-deductible kind of item for you, I am not hearing anybody contradict that. I resent that very much, because then everybody else is still paying those very, very high prices. So just know something is going to happen here if you don't decide in your own interests to lower those prices so people don't have to die. I yield back.

Ms. DEGETTE. The gentlelady yields back. The gentleman from California, Mr. Peters, is recognized for 5 minutes.

Mr. PETERS. Thanks. I have heard a lot of this discussion and it has been very edifying for me. Actually, I don't want to blame you for a system that we have set up here that encourages these bizarre incentives. The fact is that it is a system that incentivizes people to charge higher list prices so they can give rebates that give them access to customers.

I am pretty much a believer in markets. Someone called this a free market. This is really not. I don't think that we should suggest that this is the kind of competition that is going to take care of our problems. What we have here is what economists call a "market failure" at best. That is when it is appropriate for government to take action in a capitalist system. I think most people agree with that, and I think that is what we are going to see.

We are going to have to take out the incentive, this crazy incentive to charge higher prices so that you can get the customers and no one knows what the real prices are. I mean it is impossible for us to understand, you know, we have access to all this information, this is a really, really opaque system and so we are going to have to change that.

I appreciate the input. I don't ever suggest that companies aren't going to make money when they are allowed to do it. I just think that this is a perverse system that has to be changed so that if we want competition, we get real competition. But this system of rebates is really encouraging an anti-competitive behavior.

Also, I know that—I will just express a concern and this is in the courts. But, you know, now we have companies owning PBMs and plans without any assurance of the relationship between the sister companies, the PBMs and the plans. Again, I think there is a real risk of anti-competitive behavior.

I mean, I think you have come here and done the best job you can answering these questions. It is a system that no one should have to apologize for, but it is a system that we are going to have to change here in Congress; and I think that is what you will see going forward. I yield back.

Ms. DEGETTE. The gentleman yields back.

We now have several members who are not on this subcommittee but who have been gracious enough to be here for most of all of the hearing, and I appreciate their attendance and input. I would like to first recognize Congressman Bucshon for 5 minutes.

Mr. BUCSHON. Thank you, Madam Chairwoman.

I was a physician before I was in Congress, so these types of issues are extremely important to me. For me it is all about people and taking care of people, making sure especially when it is a life-sustaining drug. I appreciate all of your input. It is a system that needs changed.

We did a hearing last Congress and we had eight stakeholders in the entire supply chain and we pretty much got this, you know, the whole time, and I get that. I am not blaming anybody. I am just saying I think it is just, we have developed a system over time that is going to need changed. I am going to have questions for both the PBMs and the companies.

Dr., is it Dutta, yes, I understand that representatives from your company testified in front of the Senate Finance Committee yesterday. My understanding is that your company was asked questions about contracting practices and relationships with manufacturers. I would like to just follow up on those and then Ms. Bricker and Mr. Moriarty can comment also.

Can you talk about the following: Has your company ever proposed in contract or otherwise demanded that manufacturers give advance notice of list price decrease? I remind you, everybody, we are all under oath here, so, and we have access to information potentially that could counteract a questioned answer that isn't accurate.

Dr. DUTTA. Yes.

Mr. BUCSHON. OK. And then the manufacturers pay a higher fee, a rebate, if list prices do not increase above a certain percentage in that contract year? So, for example, if they don't increase their list price above a certain percent that they may have to pay a higher fee or rebate for that drug?

Dr. DUTTA. I'm not aware of that.

Mr. BUCSHON. OK. And that manufacturers pay a certain rebate amount even if they decrease their list price?

Dr. DUTTA. I'm not—

Mr. BUCSHON. My point is if you have a list price here and the company says, "We are going to go down to here," and the rebate was based on the higher list price, does that amount stay the same?

Dr. DUTTA. I'm not aware of that.

Mr. BUCSHON. OK.

Same questions, Ms. Bricker, is do you have contractual or otherwise demanded that manufacturers give advance notice of list price decrease?

Ms. BRICKER. No, we welcome lower list prices.

Mr. BUCSHON. OK, great. And that manufacturers pay a higher fee or rebate if list prices do not increase above a certain percentage in that contract year?

Ms. BRICKER. No.

Mr. BUCSHON. OK. The manufacturers pay a certain rebate even if they decrease their list?

Ms. BRICKER. No.

Mr. BUCSHON. OK. We hear that they do.

But, Mr. Moriarty, same thing, I mean do you have contractual relationships that otherwise demand that the manufacturers give you advance notice of decrease in the list?

Mr. MORIARTY. No.

Mr. BUCSHON. OK, great. The manufacturers pay a higher fee or rebate if list prices do not increase above a certain percentage in a contract year?

Mr. MORIARTY. No.

Mr. BUCSHON. OK, great. The manufacturers pay a certain rebate amount even if they decrease the list?

Mr. MORIARTY. No.

Mr. BUCSHON. OK.

Mr. MORIARTY. We are all about net price.

Mr. BUCSHON. Understood.

I am going to focus on the 340B program real quickly. I have been an advocate for reforming that program. Information that Novo Nordisk provided to the committee indicated that many of Novo Nordisk's insulin products are at penny pricing in the 340B program. Moreover, information Novo Nordisk provided the committee showed that for one of these insulin products at penny pricing the number of packages provided to 340B entities increased from just over 270,000 packages in 2014 to over 735,000 packages in 2018. That is more than 172 percent increase in the number of packages supplied to 340B entities, and many of the Novo Nordisk other insulin products also saw a significant increase in the number of packages sold in the 340B program during this period.

Can you explain the impact that the 340B program has had on Novo Nordisk's pricing in the private and commercial markets?

Mr. LANGA. We have over 18,000 facilities, I believe, at this point roughly and it is at penny pricing. So it's literally 99.9 percent, and the packaging is, I believe as you reference it so; and has been going up. Is the question its influence on the commercial market?

Mr. BUCSHON. Yes, I mean because of that, because of its penny pricing and the volume has gone up dramatically, has that had an effect on the overall pricing structure in the rest of the marketplace, essentially?

Mr. LANGA. I think the challenge has been the 340B entities and who actually gets the designation and not. I think that's been more of the complexity and the challenge than it has been the spillover.

Mr. BUCSHON. OK.

Mr. Mason, same thing. I mean 340B has dramatically expanded as we all know, right?

Mr. MASON. A similar question, I mean obviously it does take away our net sales. If those are legitimately helping, you know, individuals that need that help we're fine that our product is going—

Mr. BUCSHON. I understand that. I mean, but, and quickly. I am out of time.

Ms. TREGONING. Yes. I think the issue is the heavily discounted products that go into the 340B system. But are those heavily discounted prices making their way to patients.

Mr. BUCSHON. Yes. I am going to just quickly say, with your indulgence, Madam Chairwoman, that in the 340B program I firmly believe based on this subcommittee's report that was released last Congress that we need to seriously look at and reform the 340B program; so that it continues to exist for the hospitals and patients that need it, but add a degree of transparency because it is spiraling.

Thank you, I yield back.

Ms. DEGETTE. I thank the gentleman. The Chair now recognizes the very, very patient woman from California, Ms. Barragán, for 5 minutes.

Ms. BARRAGÁN. Thank you very much.

You know, I am sitting here, and I have been hearing this back-and-forth for the last couple of hours, and the way I think I would summarize this is it sounds like we are playing a middleman. It just sounds like we are playing a middleman for prescription drugs to be on a preferred list. That is not just to put all the blame here, but then these list prices have just been skyrocketing and then when we ask about pricing. What we are hearing back from the drug companies is, well, the net price is actually declining. Last time I checked I think Lilly was doing pretty good. Wouldn't you say so, Mr. Mason? Why don't you tell me what the revenue was for this coming year? What is Lilly's revenue this coming year?

Mr. MASON. \$21 billion.

Ms. BARRAGÁN. OK, I saw \$25.3 billion for the coming year. Your CEO in 2014 was making 14.5 million in a pay package. That was in 2014. The new CEO, 2018, is making \$17.2 million in a pay package. You guys are doing okay. I would think so. The American people sees that, and they say, "Why can't we just get pricing for insulin, a lifesaving drug that we need? Not that we want, but that we need." And they say Congress has to do something.

When you see what, when you hear what is happening here today that is exactly what is going to have to happen. I don't see anything happening here. I mean, look, I represent a congressional district that is a majority minority. People of color are disproportionately impacted by diabetes, Latinos and African Americans. I happen to represent a district that includes Compton and Watts, very low-income, working class families who are struggling. My re-

port says there is over 80,000 uninsured there, a lot of people who probably can't afford to pay for their insulin.

Do you all recognize that YOUR pricing policies and this system is causing people to die every day? Do you all recognize that? Mr. Mason, do you recognize that? Let me just go down the list here, yes or no, do you all recognize this?

Mr. MASON. We don't want anyone not to be able to provide their insulin. We——

Ms. BARRAGÁN. I understand that. But do you recognize that this pricing system and model is causing people to die?

Mr. MASON. We need to do something about it collectively.

Ms. BARRAGÁN. OK, that is a yes.

Mr. Langa?

Mr. LANGA. We recognize the model is certainly a challenge, yes.

Ms. BARRAGÁN. You are playing a role in that model. Let's not mince any words here, is these companies and the PBMs are playing a role in this model and that is why we are having this hearing is because we are trying to get to the bottom of it.

Ms. BARRAGÁN. Ms. Tregoning.

Ms. TREGONING. Yes, we recognize that's happening and that's why we put in place the programs, to address the inadequacies of the current system so that that doesn't happen, so people aren't forced into rationing their insulin. We don't want to see that.

Ms. BARRAGÁN. Mr. Moriarty?

Mr. MORIARTY. There's no question there's a portion of the population where this needs to be addressed very directly, no question.

Ms. BARRAGÁN. Ms. Bricker?

Ms. BRICKER. Absolutely there are patients falling through the cracks. We exist only to make medication more affordable and——

Ms. BARRAGÁN. OK. I am not obviously going to get you to tell me that you are a part, because I mean, and the reality is what we heard today that that is what is happening here. You know, I wish that you all would just come together and collaborate.

A moment ago, Ms. Bricker, I believe you are the one who said that the way you were able to get the \$25 plan and the deal that you were able to get for the insulin, the new program that you just rolled out, was that you collaborated together, that you worked together. So if you could do it there, how come you all can't do it for others, right? And so, this is where Congress has to step in and do something. It is because of profits. It is because of greed. The American people are tired. And when people die, when people die and that is what is happening, make no mistake about it, we hear about it. The country hears about it and it is outrageous. It is completely outrageous.

I want to end quickly on the Medicare Part D. You know, in 2018, more than 43 million seniors enrolled in Part D plans. Currently, the Government is prohibited from negotiating directly with the drug manufacturers on behalf of Medicare Part D enrollees. If this prohibition were lifted the Government would be able to provide the leverage needed to bring down prescription drug pricing.

On a yes or no real quick because I only have 10 seconds, starting on the end, yes or no, do you support Medicare being able to negotiate drug prices under Part D?

Mr. MASON. Prices are getting better in Part D——

Ms. BARRAGÁN. Yes or no, would you support negotiating drug prices under Medicare Part D?

Mr. MASON. Just don't think they're needed.

Ms. BARRAGÁN. OK.

Mr. LANGA. I think everything we would consider, if it helped the patient.

Ms. BARRAGÁN. So that is a yes?

Mr. LANGA. I think we'd consider everything. I think the fair market, the free market that's playing right now is working because we have some of the heaviest discounts in Part D.

Ms. BARRAGÁN. It is not working because people are dying, and they can't afford it.

But next?

Ms. TREGONING. The PBMs are very effective negotiators. The question: is what do we do with the results of those negotiations?

Ms. BARRAGÁN. You don't have an answer on whether you support Medicare being able to negotiate drug prices under Part D?

Ms. TREGONING. Don't support direct negotiation because the PBMs are effective negotiators.

Ms. BARRAGÁN. You do not. OK.

Mr. MORIARTY. We do not. We drive very effective discounting.

Ms. BARRAGÁN. OK.

OK, Ms. Bricker?

Ms. BRICKER. Similarly, yes. The Government—

Ms. BARRAGÁN. You do not?

Ms. BRICKER. Do not support.

Ms. BARRAGÁN. OK.

Mr. Dutta?

Dr. DUTTA. We do not.

Ms. BARRAGÁN. OK. I can understand why that might be the case. It is unfortunate, but my time is up. I yield back.

Ms. DEGETTE. Thank you. I thank the gentlelady.

I am now pleased to recognize the gentleman from Georgia, Mr. Carter, for 5 minutes.

Mr. CARTER. Thank you, Madam Chair, and thank you for allowing me to participate in this.

Ladies and gentlemen, thank you for being here today. Just a full disclosure, currently I am the only pharmacist serving in Congress. I practiced pharmacy, community pharmacy, independent community pharmacy for over 30 years. You know, I remember and just FYI, I started when I was ten. But I can remember that—I can remember when PBMs evolved. I can remember when PSC was nothing more than a processor. That is all they did was process claims before PBMs got involved in setting up formularies. I can remember ordering directly from drug companies and not going through a wholesaler or anyone, just getting a shipment every week, a delivery every week from Eli Lilly or any other of the companies, Upjohn, or any of the number of companies that we ordered from.

You know, my colleague, Mr. Tonko, mentioned earlier about patients having to make choices between eating and between paying for their medications. I have seen it firsthand. I have witnessed it firsthand.

Ms. Bricker, you said you were a pharmacist and practiced in community forums. I don't know what your experiences were. You are obviously a lot younger than me, but at the same time I can tell you I have seen it. I have seen patients at the counter having to make a decision between buying medicine and between buying groceries. I have seen mothers in tears because they couldn't afford their medications. I have witnessed it firsthand. I was the boots on the ground there. That is why I am so passionate about that.

I wanted to start with you Mr. Langa. During a briefing with committee staff, I don't know if it was you or a member, or a representative of your company; but they said that list prices started to increase more rapidly around the same time that there started to be more consolidation throughout the drug pricing supply chain, and that there have been increasing demands on rebates. Has consolidation impacted the list price of medications?

Mr. LANGA. I think it was a factor. I think that as the PBMs today, as I mentioned the three here today represent almost 220 million covered lives or 80 percent of the lives, so.

Mr. CARTER. And that is probably, the three here today I believe represent over between 70 and 80 percent of all the PBMs in America.

Mr. LANGA. Correct. I think that as the consolidation that purchasing power got bigger, the rebate challenges got heavier.

Mr. CARTER. Absolutely.

Mr. Mason, would you agree with that? And in fact, I believe that you responded to a letter and said the same thing.

Mr. MASON. Yes.

Mr. CARTER. OK.

I would like to ask you, Mr. Moriarty, you are with CVS Health. CVS is a drugstore, right?

Mr. MORIARTY. That's correct.

Mr. CARTER. Caremark is the PBM.

Mr. MORIARTY. That's correct.

Mr. CARTER. And that is owned by CVS, the same company?

Mr. MORIARTY. That's correct.

Mr. CARTER. Aetna Insurance is the same company?

Mr. MORIARTY. That's correct.

Mr. CARTER. OK, so we got Aetna the insurance company, we got Caremark the PBM, and we got CVS the drugstore, all the same company, right?

Mr. MORIARTY. That's correct.

Mr. CARTER. OK.

Ms. Bricker, I believe that Express Scripts, you are here today representing the PBM?

Ms. BRICKER. Yes, I am.

Mr. CARTER. You are also—you just bought out CIGNA Insurance. That is right?

Ms. BRICKER. CIGNA acquired Express Scripts.

Mr. CARTER. CIGNA acquired Express Scripts, and you also have your own mail-order pharmacy; is that correct?

Ms. BRICKER. We do have a mail-order pharmacy.

Mr. CARTER. OK.

Dr. Dutta, same thing with you. Optum is the PBM, United Healthcare is the insurance company, and you also have your own mail-order pharmacy; is that correct?

Dr. DUTTA. Optum and United Healthcare are sister companies, yes.

Mr. CARTER. You do have a mail-order pharmacy that you own as well?

Dr. DUTTA. OptumRx has a mail-order pharmacy.

Mr. CARTER. Yes. okay, that is a long yes answer. Nevertheless, when you have been saying during these hearings that you are returning money to the plan sponsors, can you define plan sponsors for me? Is that the insurance companies?

Mr. Moriarty?

Mr. MORIARTY. It is the employers, State and Federal—

Mr. CARTER. The insurance, are you sending the money back to the insurance company?

Mr. MORIARTY. As well as health plans, but it's much more than just health plans. Yes, sir.

Mr. CARTER. You are sending it back to—and, Ms. Bricker, you are sending it back to the insurance companies?

Ms. BRICKER. So we send back to the clients that hire us. Those are employers—

Mr. CARTER. At the end do you send it back to the insurance—please remember you are under oath here. Let's get on. Do you send it back to the insurance companies?

Ms. BRICKER. In the event that the plan sponsor is an insurance company, yes.

Mr. CARTER. Right.

Ms. BRICKER. But that's not the only—

Mr. CARTER. OK.

Dr. Dutta, same thing with you?

Dr. DUTTA. In the event that the plan sponsor is the insurance—

Mr. CARTER. OK, same thing. So essentially you are the PBM managing money and you are sending the money back to another company that you own. In some cases that could be the case; isn't that right, Dr. Dutta?

Dr. DUTTA. So we have many health plans that—

Mr. CARTER. I understand that. But it is possible you could be sending it back to the—owned by the same company. So this vertical integration that we are talking about here that I have been on the FTC and the Department of Justice about, that is something that certainly we need to be aware of.

Boy, 5 minutes flies, let me tell you. But before I relinquish my time, I want to congratulate all of you because you have done something here today that we have been trying to do in Congress ever since the 4 years and 3 months that I have been here and that is to create bipartisanship, because what you have witnessed here today is bipartisanship.

This is going to end. I have witnessed it. I have seen what you have done with the PBMs. I have seen what you have done with DIR fees. I see what you are trying to do now with GER fees and BER fees. Let me tell you, what the CMS is proposing in the way of doing away with DIR fees and the way of having discounts at

the point of sale, that is going to happen. We are going to make sure that happens and that is going to bring more transparency to the system, and we are not going to stop there.

Thank you, Madam Chair, and I yield back.

Ms. DEGETTE. Thank you, Mr. Carter. I was just saying I never thought I would see the day when Buddy Carter was channeling Jan Schakowsky. Congratulations.

I now want to recognize Mr. Guthrie for closing questions and a statement.

Mr. GUTHRIE. I just want to close and when the Chair and I were discussing having the hearing we thought insulin was a proper one to have. One, I know it is different than 100 years ago today. But we had a lady before, a doctor, physician from Yale that said that there was—held up an insulin and said this is the same insulin from the 1990s as it is today and the price has moved forward.

We wanted to—because we wanted to look at the entire system, but we thought if we looked at one drug that affects almost—like I said, I have two nieces with diabetes—it affects almost every family, that we could look at what is going on and then we could extrapolate to bigger.

I will tell you, and you were talking about Ms. Schakowsky, my friend Ms. Schakowsky from Illinois, she also talked about President Trump in saying that this is important to him. My experience with him in meeting with him is that drug pricing is important to him, so it is everybody. It is uniting everyone.

I am going to be quick. I know 5 minutes went fast before, I didn't get all my questions. I am not going to ask a question because that is not what I have been recognized for. But innovation is important. I saw a film yesterday of a father talking about his daughter, I don't know if "cured" is the right word, but not having any symptoms from sickle cell. I mean it is just—Hepatitis C, you can take with, and you talk about medical devices. You can do the artificial pancreases here.

So innovation and having a market-based system and a free enterprise system is absolutely important and—but what we are trying to get at with this is, and hopefully you can see our frustration, is that we see the pharmaceutical companies say, "Our net price is going down." We see the list price going up. I have friends here from Bardstown that are in the Buddy Carter situation, are community pharmacists, and they see, have described to me situations that he just described and they have to pay the list price to sell to somebody who is not through the—when they sell, so it is a cash flow to those kind of businesses.

What we are trying to figure out is if the net price is the net price, then why isn't that what is paid to the—if the idea is we are going to get the lowest price for our insurance companies, then why isn't selling something for \$135 that is costing them \$135 better than selling something 300 or \$400 and getting 300 or \$400 back, other than saying I saved you that money? Just trying to figure out where the money is going and so this has been informative.

I think one question I wanted to ask that I am going to do for the record is, so what you put on the formulary, is it better for a high list price with a lower net or that is better for the insurance company, but it is not as good for a—if it is just a lower net price

or just lower list price, it is actually lower for the consumer going to the counter at the pharmacy?

This is just hopefully the beginning of a series of hearings and it has been informative. We do appreciate you willing to come here and your testimony and trying to inform us because we do have to make some decisions. We don't want unintended consequences because you could get into—if you get into price controls you get into rationing and you get into shortages and that is not where we want to—that is not where I want to go. We want people to have a fair price that they can pay and if they can't pay to have the assistance to have that because it is lifesaving.

Thank you for your indulgence and I yield back.

Ms. DEGETTE. I thank the ranking member, and I do want to thank the witnesses. I know people asked you hard questions. It was important to us to get everybody in here, and I think we can all agree that the system is broken, and it has grown up in a way over time that people didn't anticipate. But here is the thing. The people who are suffering are the patients. In the case of insulin, the people who are suffering are people who need insulin every second of every minute of every day or they will die, and that is the issue that we have here.

I now, having done this investigation last year with my colleague from New York, Tom Reed, and now doing this investigation, I think I have a pretty good grip, and I think the members of this committee are getting a better and better grip of what is going on. And what is going on is the system has grown up in this country where we are continually—it is a smoke-and-mirror system where we are continually increasing the list price of insulin in order to try to do negotiations to somehow get the price of insulin down.

But let's look at the reality of the situation. The members of this panel kept saying over and over again net prices of insulin have gone down and one person even said that nobody pays list price, they all pay net price. But that is not exactly true.

So I just want to give you the example of Humalog, because Humalog is one of those insulins, it is not 100 years old, but it is over 20 years old and in 2001, Humalog cost \$35 a vial. Today, no change to Humalog—it is not Tresiba, which by the way Tresiba is not an insulin, it is another drug to help absorption of insulin that is given to type 2 diabetics—so Humalog, it is still the same formulary. It is \$275 today for a bottle of the same insulin that I bought for Francesca when she was six years old, and the generic Humalog that Lilly has come up with, good news, it is only \$137 a bottle. So it is still way beyond where it was in 2001.

Well, now Sanofi has a new generic alternative, Admelog. I just sat here and looked and Admelog, it might not cost as much as Humalog, but it costs over \$200 a bottle. So let's not kid ourselves that the generic equivalent of this is really any cheaper for that young woman in my district who doesn't have insurance who is desperately trying to find two bottles of insulin every month. That is \$400 for her even if she bought that.

When you say nobody is paying list price, there are people paying list price. The people who are paying list price are the people who have high-deductible plans who have to pay for the list price when they go in to the pharmacy and they are on their deductible, the

people who are in the doughnut hole of Medicare Part D, and the people who are uninsured.

I know all of the, everybody here, the PBMs and the pharmaceutical companies all have these efforts to give cheaper insulin to people like this, but I am going to tell you, the lady I talked to in Denver, she didn't know how to get that insulin. She had no idea how to get it, and our witnesses last week said many people in that situation don't. It is not a solution to the problem, it is just a temporary Band-aid and it is one that we have to stop with a whole-sale innovation.

Let me just say, finally, this. It is not like the pharmaceutical companies or anybody else in the system is doing this for a public interest reason. The pharmaceutical companies had \$323 billion in profits last year. The PBMs had \$23 billion in profits last year. And so everybody is making a profit and the people who are really suffering here are the people who either have to pay list price or even after their deductible have to pay an unacceptable price and nobody here in this room wants that.

What we are going to do, we are going to get together in a bipartisan way and we are going to work with all of you, plus everybody else in the distribution center, to figure out how we can provide insulin to diabetics at a cost that they can afford and we are going to do that as quickly as we can. So as you heard we are having an ongoing investigation here. We are prepared to talk to you now and we are prepared to bring you all back in July or in September to talk about the progress that we have made, because this is not optional and it is going to happen. I want to thank you all again for coming today and we are not going to have any more testimony, but I really want to thank you for coming and I want to thank you for being part of the solution and not a continuing part of the problem.

In closing, I will remind members that pursuant to committee rules they have 10 business days to submit additional questions for the record to be answered by witnesses who have appeared before the subcommittee. I ask that the witnesses agree to respond promptly to any such question should you receive any, and with that the subcommittee is adjourned.

[Whereupon, at 2:37 p.m., the subcommittee was adjourned.]

[The article appears at the conclusion of the hearing.]

6/13/2019

Protesters at Sanofi in Cambridge decry high price of insulin - The Boston Globe

## Protesters at Sanofi in Cambridge decry high price of insulin

By Allison Hagan Globe Correspondent, November 16, 2018, 5:17 p.m.

Two mothers Friday tried to deliver the ashes of their two diabetic children to the Cambridge offices of drug giant Sanofi to protest the high price of insulin, which the company manufactures. The women said their adult children died while rationing the drug to save money, after losing their health insurance.

Antroinette Worsham of Cincinnati, Ohio, and Nicole Smith-Holt from Richfield, Minn., were joined by about 75 protesters. According to the Brookline-based Right Care Alliance, a patient advocacy coalition that organized the protest, Paris-based Sanofi is one of three insulin manufacturers that in recent years have marked up prices by as much as 5,000 percent.

The protesters stayed across the street while the two mothers attempted to walk through the Memorial Drive parking lot with small containers holding the ashes, but company security officials ordered them off the property, said Aaron Toleos, a spokesman for Right Care. Toleos said police on the scene told the women that “if you choose not to leave, you will be arrested.” No arrests were made.

“We continued with the protest and letting them know the price of their product is killing people when it’s intended to save their lives,” said Smith-Holt, whose 26-year-old son, Alec Raeshawn Smith, died last year.

6/13/2019

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Nicole Smith-Holt of Richfield, Minn., held a vial with the ashes of her son, Alec, who died at the age of 26 from insulin rationing. (JOHN TLUMACKI/GLOBE STAFF)

Worsham's daughter, Antavia Lee Worsham, 22, also died in 2017. Right Care said they, and one other diabetes patient, lost their lives because they were forced to cut back on their medication to save money.

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Antoinette Worsham held a vial of ashes from her daughter, Antavia Lee Worsham, who died last year. (JOHN TLUMACKI/GLOBE STAFF)

Nicolas Kressmann, a spokesman for Sanofi, said the company is exploring innovative ways to reduce out-of-pocket costs for patients. He said the company's security prevented the protesters from entering the company's office because of safety concerns.

"We want to ensure everything works as well as possible for employees and the protesters. We don't want any accidents or any situation," he said.

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Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Hearing on  
“Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin”

April 10, 2019

Mr. Mike Mason, Senior Vice President, Lilly Connected Care and Insulins Global  
Business Unit, Eli Lilly and Company

The Honorable Joseph P. Kennedy III (D-MA)

1. At the Oversight Subcommittee hearing on April 2, 2019, the witnesses spoke about the ineffectiveness of patient assistance programs and testified the programs are untimely, unworkable, and a barrier to accessing insulin. Whether the programs' criteria are too difficult to find or the application processes require already sick people to jump through hoops, there is wide consensus the programs are a cruel substitute for lower list prices.

Regarding patient assistance programs specifically for insulin at your company, please provide a clearer picture of how they operate by answering the following questions.

- a. Where can patients find information on eligibility and criteria for the programs?
- b. What are the eligibility criteria for the programs?
- c. What information and documents must patients submit in order to qualify for the programs?
- d. What number of patients apply for the programs each year, what number are approved, and what number are denied?
- e. What are the ten most common reasons your company denies a patient's application?
- f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?
- g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for insulin in 2018?

Eli Lilly and Company (“Lilly”) understands the importance of ensuring that our various insulin products are both accessible and affordable to individuals with diabetes. We have a number of programs in place to increase affordable access to our insulins. Information about these programs, their eligibility criteria, their utilization, and Lilly's efforts to make them widely available is set forth below.

Promoting affordable access begins with ensuring that our insulins are available to patients with insurance, which includes both private insureds and those covered by Medicare

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Part D. Like other manufacturers, Lilly competes for placement on insurance formularies on the basis of product attributes like efficacy and safety, and by providing rebates to reduce the cost of insulin to pharmacy benefit managers (“PBMs”), payers, and patients. In 2018, for Basaglar, Humalog, and Humulin, Lilly paid approximately \$4.4 billion<sup>1</sup> in rebates, discounts, and other price concessions, or over 50% of the \$8 billion in gross sales of those products. By paying these rebates, Lilly ensures that its insulins are available to patients with insurance, who typically have low out-of-pocket costs.

We recognize that despite the rebates Lilly pays to ensure formulary access, some individuals remain exposed to high prescription drug costs. These patients have a real and pressing need for immediate solutions—particularly those who rely on medications to treat life-threatening, chronic conditions like diabetes. For this reason, Lilly has instituted multiple programs designed to reach each of the segments of people who need assistance affording their insulin. These programs work in a variety of ways. The Centers for Medicare and Medicaid Services (“CMS”) narrowly define pharmaceutical manufacturer-sponsored “patient assistance programs” as those that “provide financial assistance or drug free [sic] product (through in-kind product donations) to low-income individuals to augment any existing prescription drug coverage.”<sup>2</sup> Lilly provides in-kind product donations to charitable organizations, including Americares, Direct Relief, Dispensary of Hope, and Lilly Cares, separate non-profit organizations that conduct “patient assistance programs” for low-income individuals.

To fill additional gaps in coverage, Lilly has implemented other programs to promote access and affordability that may be relevant to your inquiry but do not fall within the CMS definition of a “patient assistance program.” Below, we provide information on the range of initiatives undertaken by Lilly in addition to product donations.

- **Insulin Lispro Injection:** We recently launched the authorized generic (“AG”) version of Humalog, Insulin Lispro Injection (“Insulin Lispro”). Insulin Lispro has a 50% lower list price than its identical medicine, Humalog U-100 and is available in both vial and KwikPen form. We sought to bring a lower-priced version of our product to the market because we recognized that Lilly’s other solutions, though important, still left some people vulnerable to high out-of-pocket costs for insulin. We expect the introduction of Insulin Lispro to particularly benefit individuals in the deductible phase of their coverage period, as well as those enrolled in Medicare Part D who are in the coverage gap. The patients who benefit from Insulin Lispro in these periods should see their out-of-pocket costs cut in half. Because of government restrictions, the over 500,000 individuals taking Humalog who are enrolled in Part D do not have access to as many of our other solutions as people covered by commercial insurance plans. By introducing this AG version, Lilly can provide a lower-

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<sup>1</sup> This figure includes: rebates for formulary access, value-based agreements, price protection penalties, patient adherence support programs, and incremental rebates associated with product bundling. This figure also includes administrative fees, which PBMs require and which are categorized as price concessions for purposes of government price reporting. These figures do not include discounts associated with mail order or cash card programs facilitated by a PBM, since they neither contribute nor are tied to conditions affecting coverage of a product.

<sup>2</sup> <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html>.

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priced insulin quickly while maintaining access to branded Humalog, on which well over one million people currently depend.

- Automatic Discounts<sup>3</sup>: Lilly also offers savings directly to people in the high-deductible phase of their insurance plans by capping their prescription cost at \$95 at a retail pharmacy. When a person in a high-deductible insurance plan fills a prescription for a Lilly insulin, the individual generally will pay no more than \$95 out of pocket at the pharmacy, and Lilly will pay the remainder of the cost.<sup>4</sup> The discount is automatically applied at the point of sale, and therefore has an immediate impact on the cost paid by the insured person. This occurs when the insurance claim is processed and does not require the individual to enroll in any programs or request that the savings offer be applied.
- Co-Pay Cards and Cash Savings Cards (collectively, "Savings Card Programs"): Lilly provides various Co-Pay Cards and Cash Savings Cards that allow patients to obtain Lilly insulins at lower prices during the high-deductible phase of a commercial insurance plan or when they are paying cash because they do not have insurance coverage. These cards typically are used when the Automatic Discounts discussed above are not available at a particular pharmacy or for patients paying cash. A Co-Pay Card is a physical or virtual card presented at the time a prescription is filled where the patient discount is adjudicated as a secondary payer in addition to the patient's insurance. Cash Savings Cards are physical or virtual saving cards for patients without commercial insurance where Lilly provides a discount to the patient that is adjudicated at the point of sale with Lilly serving as the primary payer.
- Point-of-Sale Savings Programs: Since 2017, Lilly has participated in Blink Health ([www.blinkhealth.com](http://www.blinkhealth.com)) and Inside Rx ([www.INSIDERx.com](http://www.INSIDERx.com)) savings programs that offer savings of up to 40% off the list price of Lilly's most commonly prescribed insulins. These programs are available to people through smart phone applications and offer savings at the point of sale. Our participation in these programs was an initial step to provide discounts to people on Lilly insulins who have commercial insurance or are uninsured.
- Lilly Diabetes Solution Center: Recognizing that some of the solutions described above will not help people unless they know about them, Lilly launched the Lilly Diabetes Solution Center ("LDSC" or the "Solution Center") in August 2018. The Solution Center is a patient-focused helpline staffed by medical professionals that connects people living with diabetes to any of Lilly's various resources and solutions based on their individual needs. These solutions include savings cards (requiring no paperwork and no application), an immediate emergency supply of insulin, or information about one of the clinics that can offer free insulin that Lilly has donated. The LDSC also can connect patients to Lilly

<sup>3</sup> Consistent with HHS OIG guidance on copayment coupons (OIG Special Advisory Bulletin—Manufacturer Copayment Coupons September 2014), the automatic discount and Co-Pay Assistance Programs are not intended to be utilized where payment may be made, in whole or in part, under a federal health care program.

<sup>4</sup> Significantly, the portion that Lilly pays is counted towards the patient's deductible.

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Cares. Lilly has publicized the LDSC through press releases, social media channels, and advertising campaigns—including direct-to-consumer print ads—that directly target people with diabetes, the general public, and specific communities of color with a higher risk of diabetes.

To access information on Lilly's affordability programs, including eligibility requirements, patients can visit [www.insulinaffordability.com](http://www.insulinaffordability.com), a Lilly website that provides information on the LDSC, Point-of-Sale Savings Programs (referred to on the website as "Discount Programs"), and Savings Card Programs. They can also call the LDSC, which provides information on many programs. The number for the LDSC is (833) 808-1234. In addition to helping patients enroll in these programs, the LDSC will also connect eligible patients with the separate non-profit Lilly Cares. Information regarding Lilly Cares and its requirements can be obtained from its website: <https://www.lillycares.com/resources.aspx>.

Lilly's affordability programs, including the Automatic Discounts, Savings Card Programs, and the Point-of-Sale Savings Programs, are readily available to patients. They require no applications and have only limited eligibility requirements. As noted above, the Automatic Discounts take place when the insurance claim is processed and do not require the individual to enroll in any programs or request that the savings offer be applied. In fact, individuals may not even be aware of these "buy-downs" or may be surprised by them. Our Savings Card Programs are broadly available to patients with commercial insurance or paying cash. To qualify for these programs, the patient must be a U.S. resident, be 18 or older, have a prescription for a Lilly insulin, and not have government insurance. There is no income cap. Similarly, a patient with commercial insurance may gain access to the Point-of-Sale Savings Programs simply by signing up. Lilly makes these programs as broadly accessible as possible. While patients with government insurance are excluded from the Automatic Discounts, Savings Card Programs, and the Point-of-Sale Savings Programs, this exclusion is imposed by the government, not by Lilly.<sup>5</sup>

Access to the LDSC is also broadly available to patients without an application and without satisfying any additional eligibility requirements. When a patient calls the LDSC, she is connected with a healthcare professional who assesses which assistance program may be the best fit. If the patient expresses an urgent concern about accessing medication, the Lilly representative's first step is to identify ways of addressing that need. For instance, the representative may be able to offer a free month's supply of insulin. Once the immediate need has been addressed, the healthcare representative moves to a conversation about longer-term solutions. Patients who meet the minimal eligibility requirements noted above are provided with assistance through Lilly's Savings Card Programs or Point-of-Sale Savings Programs. A patient who has Medicare Part D insurance is connected to Lilly Cares, since (as noted) Lilly may not, consistent with applicable government guidance, help these patients through its Automatic Discount, Savings Card, or Point-of-Sale Savings Programs. Additionally, if a patient volunteers income information indicating that the patient may be eligible for free insulin from Lilly Cares,

<sup>5</sup> Federal guidance has prevented Lilly and other manufacturers from subsidizing prescription costs for people insured through government programs such as Medicare Part D. OIG Special Advisory Bulletin—Manufacturer Copayment Coupons September 2014.

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the LDSC representative refers the patient there. The LDSC can also provide patients with a list of clinics that provide free medication in or near her zip code. Finally, LDSC representatives are also able to provide information about Insulin Lispro. There are no separate income requirements that a patient must meet to obtain assistance from the LDSC, and no paperwork is required.

Only Lilly Cares requires patients to submit an application form.<sup>6</sup> (As previously noted, Lilly Cares is a non-profit organization separate from Lilly, but for convenience, we provide publicly available information from Lilly Cares herein.) The Lilly Cares application is available at: [https://www.lillycares.com/\\_Assets/pdf/LillyCares\\_Group\\_ABApplication\\_EmgalityProgram\\_Eligibility\\_Update.pdf](https://www.lillycares.com/_Assets/pdf/LillyCares_Group_ABApplication_EmgalityProgram_Eligibility_Update.pdf). The form explains the separate Lilly Cares eligibility requirements, one of which relates to income. To access insulin drugs through Lilly Cares, a patient's household income may be no more than 400% of the federal poverty limit (\$100,400 for a family of four).<sup>7</sup>

We want people to use our solutions, and our intent is to make these solutions as easy to access as possible. In 2018, Lilly spent more than \$108 million on Automatic Discounts and Savings Card Programs, plus an additional \$3 million on Point-of-Sale Savings Programs. The amount spent on Automatic Discounts and Savings Card Programs in 2019 is expected to rise to at least \$200 million. Information from our vendors indicates that in 2018, the Automatic Discounts and Savings Card Programs served 525,403 unique patients, for a total of 1,636,797 redemptions. The Point-of-Sale Savings Programs are independently administered, and Lilly does not maintain enrollment data on those. Because Lilly's Automatic Discounts, Savings Card Program, and Point-of-Sale Savings programs do not require applications, Lilly does not have "denial" information for these programs. Utilization or denial data related to Lilly's donations of free insulin is not readily available because product donations are distributed by separate charitable organizations. The chart below, however, shows Lilly's donations of insulin from the Humalog, Humulin, and Basaglar product families from 2014 – 2018:

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<sup>6</sup> Other free clinics to which Lilly donates medicines may also require application forms.

<sup>7</sup> [https://www.lillycares.com/\\_Assets/pdf/LillyCares\\_Group\\_ABApplication\\_EmgalityProgram\\_Eligibility\\_Update.pdf](https://www.lillycares.com/_Assets/pdf/LillyCares_Group_ABApplication_EmgalityProgram_Eligibility_Update.pdf).

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Organization	Quantity of Pens <sup>8</sup> and Vials
<b>2014</b>	
AmeriCares	380
Catholic Medical Missions Board	7,200
Diabetes Camps	34,504
Direct Relief	12,344
Lilly Cares Foundation	980,352
Lilly Medicare Answers	3,488
MAP International	200
Partners in Health	6,512
Project HOPE	43,000
<b>2015</b>	
Catholic Medical Missions Board	12,700
Diabetes Camps	39,807
Direct Relief	17,696
Lilly Cares Foundation	748,540
Lilly Medicare Answers	189,449
<b>2016</b>	
Catholic Medical Missions Board	19,050
Diabetes Camps	40,284
Direct Relief	23,693
Lilly Cares Foundation	1,038,710
<b>2017</b>	
AmeriCares	23,910
Catholic Medical Missions Board	4,700
Diabetes Camps	50,587
Direct Relief	164,325
Project HOPE	1,500
Lilly Cares Foundation	928,664
<b>2018</b>	
AmeriCares	24,600
Catholic Medical Missions Board	14,900
Diabetes Camps	46,812
Direct Relief	153,900
Dispensary of Hope	23,200
Lilly Cares Foundation	1,233,096
<b>Total (2014-2018)</b>	<b>5,888,103</b>

Approval or denial data for the separate non-profit entity Lilly Cares is available through that organization's 2018 Annual Report, which states that 88% of people who applied were approved for up to a year of coverage.<sup>9</sup> According to that Report, more than 52,000 patients were provided with \$320.3 million in diabetes medication in 2018.<sup>10</sup>

<sup>8</sup> This table refers to the number of pens donated—not the number of boxes of pens donated.

<sup>9</sup> [http://www.lillycares.com/\\_Assets/pdf/Lilly\\_Cares\\_2018\\_Annual\\_Report.pdf](http://www.lillycares.com/_Assets/pdf/Lilly_Cares_2018_Annual_Report.pdf).

<sup>10</sup> *Id.*

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Lilly's various programs to promote access and affordability have different requirements for requalification. Because there are no eligibility requirements for Insulin Lispro, there are no requalification requirements. Similarly, the Automatic Discounts take place automatically and require no patient action at any time. The Savings Card Programs typically last for a year and must be reauthorized on a yearly basis. The criteria for reauthorization are the same as for initial eligibility: the patient must be a U.S. resident, be 18 or older, have a prescription for a Lilly insulin, and not have government insurance.

The last subsection of this question asks how much Lilly spent on public awareness campaigns to promote its patient assistance programs in 2018 and how much Lilly spent on advertising for insulin in 2018. Lilly has implemented a comprehensive public awareness campaign for the LDSC that uses its sales force, social media, direct healthcare provider and pharmacy communications, and outreach to elected officials and patients. Our primary efforts are focused on healthcare providers and pharmacists providing care for people living with diabetes. Our national sales force proactively promotes awareness about our LDSC offerings. They are trained to provide information about how patients can connect with the LDSC and the various affordability solutions that are available. They also encourage healthcare providers to distribute LDSC flyers, patient cards, and office magnets, which list the call center's phone number and hours.

For 2018, Lilly also spent approximately \$5.3 million on advertising the LDSC, which launched in August of that year, directly to patients. This is more than one-fifth of the amount Lilly spent on consumer awareness programs (including advertising) for its insulin products that year (approximately \$23.4 million).<sup>11</sup> And about 50% of that \$23.4 million was spent on a patient education campaign for patients who may have questions about how to start using Lilly insulin or how best to adhere to the treatment going forward.

In addition to paid advertising, Lilly promotes the LDSC through social media. Since August 2018, Lilly has published eight blog posts about the LDSC on LillyPad,<sup>12</sup> Lilly's official blog, and more than 145 social media posts on our corporate Twitter, Facebook, and LinkedIn accounts.<sup>13</sup> For example, during the federal government shutdown in 2018 – 2019, we published a blog post<sup>14</sup> and ran a paid LinkedIn advertising campaign to inform federal employees that they were eligible for discounts. We have directed more than 1,000 questions about insulin

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<sup>11</sup> Consumer expenses reflect promotional activities designed to support patients initiating insulin treatment whom already received an insulin prescription from their Health Care Provider. Examples include branded paid search advertising and printed materials for patients. Also, included are unbranded disease state education digital content sponsored by Lilly USA, LLC. This may also include branded advertising presented alongside unbranded content. These expenses, including the unbranded content, are classified as promotional advertising by Eli Lilly and Company.

<sup>12</sup> <https://lillypad.lilly.com>; see, e.g., Mike Mason, *Helping People with Insulin Affordability*, LILLYPAD (Aug. 1, 2019), <https://lillypad.lilly.com/entry.php?e=11030>.

<sup>13</sup> Lilly's corporate divisions each maintain their own social media accounts; these numbers include posts by Eli Lilly & Company and by Lilly Diabetes.

<sup>14</sup> *Help for People, Including Federal Employees*, LILLYPAD (Jan. 16, 2019), <https://lillypad.lilly.com/entry.php?e=11221>.

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affordability to the LDSC via these social media channels in response to private direct messages and public posts. We also have issued three press releases about the LDSC since its launch.

In addition, we have reached out individually to hundreds of elected state officials to alert them of the LDSC, including governors and representatives in states such as California, Delaware, Idaho, Kentucky, Maryland, Massachusetts, New Jersey, New York, Pennsylvania, and Tennessee. Moreover, during the federal employee shutdown earlier this year, we sent similar notices to reach employees who may have needed assistance during the furlough.

The costs of advertising the LDSC are only a portion of the overall costs of operating the Solution Center. In 2018, Lilly spent approximately \$3 million to staff the LDSC with healthcare professionals who answer individuals' questions. We opened the LDSC with four dedicated agents, but due to marketing efforts and increased awareness, we have had to increase our headcount by nearly 400% since our launch in August 2018, and that growth continues. Additionally, the \$3 million spent in 2018 does not account for unallocated Lilly expenses, such as training and support from Lilly employees. These expenses are in addition to the \$108 million noted above spent in 2018 on Automatic Discounts and Savings Card Programs and the \$3 million spent on Point-of-Sale Savings Programs.

Overall, our solutions are working to reduce out-of-pocket costs. Today 95% of prescriptions for Humalog in the United States cost consumers less than \$95 at the retail pharmacy, 90% cost less than \$50, and 43% cost \$0.<sup>15</sup> These figures reflect the cost for Humalog at the retail pharmacy regardless of the phase or term of the patient's health plan. Now that Insulin Lispro has launched, we hope it will be added to more formularies. At the same time, we continue to educate the diabetes and medical community about our Lilly Diabetes Solution Center so that even more people will pay less for their insulin.

2. Regarding patient assistance programs at your company for all types of medication, please provide a clearer picture of how they operate by answering the following questions.
- a. Where can patients find information on eligibility and criteria for the programs?
  - b. What are the eligibility criteria for the programs?
  - c. What information and documents must patients submit in order to qualify for the programs?
  - d. What number of patients apply for the programs each year, what number are approved, and what number are denied?
  - e. What are the ten most common reasons your company denies a patient's application?
  - f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

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<sup>15</sup> Based on IQVIA data, FIA data (August 2018 – December 2018).

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- g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for medication in 2018?**

Lilly manufactures a variety of medications in the oncology, cardiology, immunology, endocrinology, and other spaces. As defined by CMS, Lilly's patient assistance programs center on donations to Lilly Cares and other charitable organizations. The following medications are available for free from Lilly Cares: Alimta, Cialis, Cymbalta, Cyramza, Emgality, Erbitux, Evista, Forteo, Glucagon, Humatrope, Lartruvo, Olumiant, Portrazza, Prozac, Strattera, Symbyax, Taltz, Trulicity, Verzenio, Zyprexa, Zyprexa Relprevv, and Zyprexa Zydis.<sup>16</sup> Approval or denial data for Lilly Cares is available through that organization's 2018 Annual Report, which states that 88% of people who applied were approved.<sup>17</sup> According to that Report, more than 52,000 patients were provided with \$320.3 million in diabetes medication in 2018.<sup>18</sup>

The Lilly Cares application is available at: [https://www.lillycares.com/\\_Assets/pdf/LillyCares\\_Group\\_ABApplication\\_EmgalityProgram\\_Eligibility\\_Update.pdf](https://www.lillycares.com/_Assets/pdf/LillyCares_Group_ABApplication_EmgalityProgram_Eligibility_Update.pdf). The Lilly Cares oncology patient assistance program application is available at: [https://www.lillycares.com/\\_Assets/pdf/LillyCares\\_oncology\\_application\\_Program\\_Eligibility\\_Update.pdf](https://www.lillycares.com/_Assets/pdf/LillyCares_oncology_application_Program_Eligibility_Update.pdf). These applications set forth the eligibility and documentation requirements for the Lilly Care programs. Other third-party charitable organizations to which Lilly donates medication each distribute product to their network of clinics subject to their own patient eligibility requirements.

- 3. Are there any medications not on your company's patient assistance program? Please provide a list of the drugs that are available for patient assistance and those that are not a part of patient assistance programs.**

All of Lilly's insulins are covered by the programs discussed in response to Question 1. Please see Lilly's response to Question 2 for information about the non-insulin drugs available through Lilly Cares, a separate non-profit organization. Lilly Cares does not provide Adcirca, Gemzar, Glyxambi, Jardiance, Jentadueto, Synjardy, and Tradjenta. These drugs are either: (1) off patent and have competition from approved generics; or (2) are products we co-promote but do not manufacture or set associated prices.

- 4. Does your company make medication available to patients for free or reduced prices, or does it use a private foundation or other third parties to operate patient assistance programs? When your company makes contributions of medication to private foundations, such as Sanofi's Patient Connection, Sanofi's Foundation for North America, Novo Nordisk's NovoCare, Eli Lilly's Lilly Cares, or other third parties, does**

<sup>16</sup> [http://www.lillycares.com/content/lillycaresgroupa\\_druglist.html](http://www.lillycares.com/content/lillycaresgroupa_druglist.html); <https://www.rxassist.org/pap-info/company-detail?CmpId=16>.

<sup>17</sup> [http://www.lillycares.com/\\_Assets/pdf/Lilly\\_Cares\\_2018\\_Annual\\_Report.pdf](http://www.lillycares.com/_Assets/pdf/Lilly_Cares_2018_Annual_Report.pdf).

<sup>18</sup> *Id.*

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**your company correspondingly reduce its tax liability? Please provide the amount by which your company reduced its tax liability for 2018 as a result of making contributions to patient assistance programs.**

As discussed above, Lilly donates medicines to Lilly Cares, a separate charitable entity, and other charitable organizations that provide free insulin to patients. Lilly is eligible for a charitable tax deduction related to those donations computed in accordance with the relevant Internal Revenue Code and Treasury Regulations. The costs of Lilly's other patient access and affordability programs are recorded as sales reductions or operating expenses and are not eligible for a charitable tax deduction.

**The Honorable Brett Guthrie (R-KY)**

- 1. In March 2019, Eli Lilly announced that it was launching an authorized generic version of Humalog. In a staff briefing, Eli Lilly said that it anticipated providing supplemental rebates for the authorized generic version of Humalog.**
  - a. Will Eli Lilly request that Pharmacy Benefit Managers (PBMs) include both the authorized generic and the brand version on their formularies? If so, why? Does Eli Lilly anticipate that one version of the product will be preferred on the formularies over the other version of the product?**

Lilly will offer and has offered all PBMs access to Insulin Lispro, the AG version of Humalog, at the same or better net price as Humalog. We believe having both options available to patients at the same formulary status (or, potentially, to have a better status for the AG) is appropriate so that individuals in a deductible phase or individuals with co-insurance would have a lower-cost option available. Our experience to date, however, is that most PBMs continue to prefer branded Humalog even when the net cost is comparable because that option offers more total rebate dollars, and many of their health plan and employer clients value the total rebate dollars that they receive when their members purchase prescription medications. As described further below, those health plans and employers use the rebate dollars they receive to marginally reduce premiums for all of their insureds, rather than using them to reduce patients' out-of-pocket costs for insulin at the pharmacy counter. As a result, most PBMs have indicated that they are considering several approaches for Insulin Lispro, such as excluding Insulin Lispro entirely from formularies, offering the AG only on "niche" formularies, or placing the product on formulary but at a higher cost-sharing tier.

- b. Will the introduction of the authorized generic have any impact on the list or net pricing for the branded version of Humalog (e.g., will the rebates Eli Lilly offers to PBMs for Humalog change)?**

We have not increased the list price of Humalog with the launch of Insulin Lispro. Launching a lower-priced product does have other costs to Lilly, especially to branded Humalog. Since we announced Insulin Lispro, some PBMs have demanded more generous rebates on

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Humalog in exchange for formulary access. For example, where the net price of Humalog after the rebate is higher than the net price of the AG, PBMs have requested that we increase their Humalog rebates so that the net price of Humalog is at least equal to the lower AG net price. As detailed further below, PBMs' clients include health insurance plans and employer groups who value the total rebate dollars that they receive. Thus, even with the net prices the same, most PBMs appear to prefer Humalog, the product that generates more rebate dollars.

2. **There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer decides to lower the list price of the medicine. Has Eli Lilly received a letter from any PBMs or insurers requesting that it provide the PBM or insurer with notice before Eli Lilly lowers the list price of insulin or any other medicine? If so, please list the entities that have sent such a letter to Eli Lilly and describe the requirements set forth in the letter.**

- a. **Does Eli Lilly have any contractual obligations to provide a supply chain partner with notice before lowering the list price of insulin or any other medicine? If so, please list the entities and describe the contractual provisions.**

No. Lilly received the communication referenced above but did not agree to the request.

- b. **Has Eli Lilly provided any of its supply chain partners with notice of a list price decrease? If so, please describe these interactions.**

No.

- c. **What happens to Eli Lilly's rebate obligations with PBMs if Eli Lilly lowers the list price of insulin or any other medicine?**

Theoretically, the dollar amount Lilly must pay in rebates should decrease if Lilly lowers the list price of a medicine, because rebates are calculated as a percentage of, and thus fixed to, a product's list price. It is possible, however, that channel partners will seek to renegotiate agreements to increase rebate and discount percentages because their financial forecasts would have been based on a product with a higher list price.

- d. **Has the letter sent by OptumRx or any other similar requests by supply chain partners impacted Eli Lilly's decisions regarding whether to lower the list price of insulin or any other medicine? If so, please describe.**

The above-referenced letter, coupled with the commercial responses to our authorized generic Insulin Lispro, illustrates the challenges and barriers to lowering list prices. As noted above, many health plans and employers value the greater total rebate dollars that they receive

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from those medications. Consequently, some PBMs have indicated that manufacturers must maintain the total dollar amount of rebates paid to them even if the list price of a prescription medication is reduced. Indeed, the above-referenced letter proposed an alternative rebate calculation whereby Lilly would be required to pay the same amount of rebate dollars on a prescription drug with a lower list price. Such demands make it difficult for Lilly to reduce list prices and retain comparable levels of patient access on PBM formularies.

These market dynamics underscore the need for systematic reform. One proposal, which is sometimes called “first dollar coverage,” is described in more detail below.

3. **We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. For example, in Eli Lilly’s testimony, Eli Lilly described how the net price of its most broadly used insulin product decreased by 8.1 percent while the list price increased by 51.9 percent. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many PBMs that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price. Please explain.**

Lilly has always sought to make its insulin medications affordable for patients who depend on them. For years, Lilly was able to accomplish this by providing significant discounts off of the list price in the form of rebates to PBMs and other payers. These rebate payments ensured that Lilly’s insulin products were covered on PBM formularies under terms that provided affordable access for patients. In recent years, PBMs have begun to offer only one manufacturer’s insulin products on their formularies, while blocking patients’ access to competing products. PBMs have used this leverage to negotiate with manufacturers for larger rebates, placing downward pressure on Lilly’s “net prices,” *i.e.*, the amount that Lilly receives on each prescription. At the same time, increasing numbers of patients have been moved to insurance plans with larger deductibles and cost-sharing obligations, such that they do not directly benefit from the larger rebates paid by Lilly and other manufacturers. These developments have created affordability challenges for a growing number of patients, even as net prices for Lilly’s insulins have stayed flat or declined.

Unfortunately, this affordability challenge cannot be addressed simply by lowering list prices. While the PBMs’ clients, which include health insurance plans and employer groups, may prefer products that have a low net cost, they also value the total rebate dollars that they receive when their members purchase prescription medications. Many plans and employers use these rebates to subsidize lower premiums for all members. This has had the effect of increasing out-of-pocket costs for patients with significant cost-sharing obligations, especially those with chronic illnesses like diabetes. For example, Lilly pays substantial rebates even for patients who are responsible for the full cost of their insulin prescription during the deductible phase of their

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health plan. Rather than using the rebate dollars to reduce those patients' out-of-pocket costs, many health plans use the rebate dollars to marginally reduce premiums for all of their insureds.

Lilly's recent launch of Insulin Lispro, a lower-priced authorized generic version of its most popular insulin product Humalog, illustrates this dynamic. Insulin Lispro is available at a list price that is 50% less than Humalog, and the rebates Lilly has offered on Insulin Lispro would provide PBMs a net cost that is comparable to branded Humalog. However, because the list price of Insulin Lispro is substantially lower than the list price of Humalog, the total rebate dollars offered on Insulin Lispro are lower. Unfortunately, after months of contract negotiations, Lilly has only been able to gain limited formulary access for Insulin Lispro. We expect that it will be covered for less than 15% of patients with commercial health insurance and less than 25% of Medicare Part D patients.

One proposal that Lilly believes is worthy of consideration is adding insulin to preventive medications lists, which would lower out-of-pocket costs by, for instance, exempting insulin from deductibles (sometimes called "first dollar coverage"). Because of how the private health care system works today and the complexity of high deductible health plans, some people have full coverage for treatments to manage their chronic conditions while others must meet out-of-pocket and deductible requirements for the same treatments. Making people with chronic diseases like diabetes pay high prices for their medications does not make sense as a matter of public policy. While billions of dollars are spent in the United States each year on medical expenses directly related to diabetes, only 6% of that is spent on insulin.<sup>19</sup> The vast majority is spent to treat the serious and costly complications of diabetes. When people with diabetes take their medications, they live healthier lives, reducing overall health care costs. As a result, insurance design that makes insulin and other medications for chronic conditions available at low out-of-pocket costs is a matter of sound public policy. Independent actuarial analyses have shown that adding first dollar coverage for insulin patients would increase policyholders' premiums by just 43 cents per month while enabling insulin patients to affordably maintain their insulin therapy.<sup>20</sup> This would be a significant step toward a more sustainable model that addresses the unacceptably high out-of-pocket costs faced by some patients.

**4. During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are sometimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.**

**a. What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?**

<sup>19</sup> Am. Diabetes Ass'n, *Economic Costs of Diabetes in the U.S. in 2017*, at 8 (Mar. 22, 2018), <http://care.diabetesjournals.org/content/diacare/early/2018/03/20/dci18-0007.full.pdf>.

<sup>20</sup> E. Anne Jackson, Matthew Berman & David M. Liner, *Mitigating Out-of-Pocket Costs for Prescription Drugs*, MILLIMAN (Dec. 2016).

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**b. Does your company support moving to a system where administrative fees are based on a flat fee instead?**

As this question notes, manufacturers are often required to pay a specified administrative fee percentage, rather than permitted to freely negotiate the amount. Often, agreeing to these fee percentages is characterized as a “bid condition” by the PBMs—failure to acquiesce to this condition will result in an offer being rejected as “non-compliant.” Since these are non-negotiable terms, manufacturers have no choice but to accept them.

We do not believe there are any advantages to setting PBM administrative fees as a percent of product’s list price (WAC). Indeed, calculating administrative fees as a percentage of the list price can create uncertainty among manufacturers, PBM clients, and policymakers regarding the economic substance of such transactions. To the extent that such administrative fees are passed on to customers, as some PBMs have stated, it may be more appropriate to classify them as rebates.

**The Honorable Jeff Duncan (R-SC)**

1. One thing that we heard from patients and doctors last week is that insulin hasn’t changed much, so they don’t understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.

Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx’s testimony stated that “[i]nsulin has been used to treat diabetes for nearly 100 years, and “manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents.”

So, which is it? Is there innovation in the insulin market or not?

Yes, there is innovation in the insulin market as well as in the treatment of diabetes generally. Today’s modern insulins have improved substantially since 1923. That year, Lilly pioneered the manufacturing and distribution of Iletin, the first animal-based insulin. Iletin was the first real hope for treating diabetes, a fatal disease then with no effective treatment options. But Iletin was created through processes most would view as crude today—extracting insulin from animal pancreases—leading to purity and quality concerns. Decades later, modern innovation led Lilly to introduce the first recombinant DNA insulin and, eventually, the first

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human analog insulin. These improvements have been part of a dramatic change in the way diabetes is treated.

Lilly brought the first genetically engineered medicine, Humulin, to market in 1982, ending concerns about whether there would be enough animal-based insulin to serve the growing number of people with diabetes. This product saved lives by allowing the use of a biosynthetic form of human insulin. In 1996, Lilly launched another biotech insulin, Humalog, which mimics the body's own rapid insulin response and has made it easier for people with diabetes to manage their blood glucose. For evidence of the importance of this innovation, one need look no further than how much more often physicians prescribe modern insulins, like Humalog, compared to older human insulins, like Humulin. While human insulin is cheaper and widely available,<sup>21</sup> the vast majority of prescriptions for Lilly insulins are for Humalog. Moreover, not every new insulin product is widely adopted. The continued preference for Humalog demonstrates that this product was truly innovative and is still effective at helping people control their diabetes.

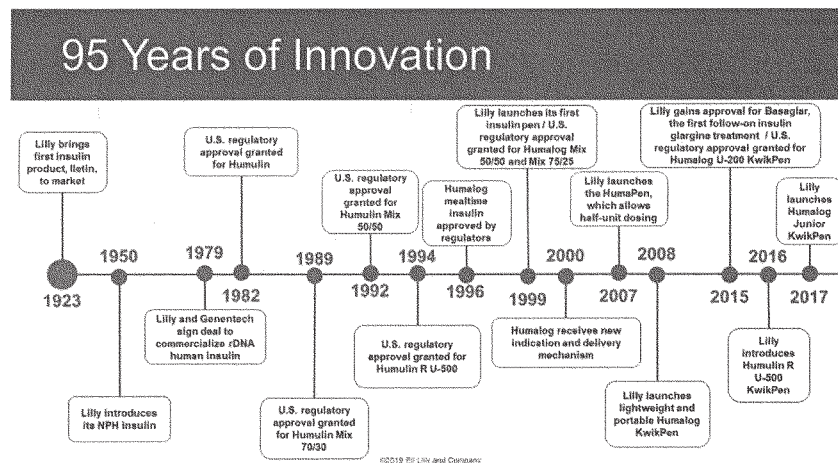
In 2015, Lilly obtained approval for the first follow-on insulin biologic, Basaglar. This product currently has a list price that is 23% lower than the list price of the most commonly prescribed basal insulin, Lantus. We also have developed a wide range of other diabetes treatments in oral and easy-to-use injectable forms that help people control their glucose levels. The wide range of therapies we offer is essential for physicians and patients to create individualized treatment plans for diabetes.

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<sup>21</sup> For example, although not a Lilly product, the availability of ReliOn—human insulin sold by Walmart at a price to the patient of approximately \$25—provides another option for patients unable to otherwise obtain access to affordable insulin. See [https://corporate.walmart.com/\\_news\\_/news-archive/2012/07/24/walmart-launches-effort-to-save-diabetes-patients-up-to-60-million-annually](https://corporate.walmart.com/_news_/news-archive/2012/07/24/walmart-launches-effort-to-save-diabetes-patients-up-to-60-million-annually).

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A timeline showing some of Lilly's significant insulin advancements is set forth below:



Before the discovery of insulin, a child diagnosed with Type 1 diabetes at age 10 typically died within 2.3 years of diagnosis. Insulin was literally life-saving: It expanded the life expectancy of the average person with Type 1 diabetes into the early 40s, and eventually to where it is today in the late 60s. But our work is not done. The life expectancy of a patient diagnosed with Type 1 diabetes is still 11-12 years lower than that of the average American. Our hope is that one day the life expectancy for a person diagnosed with diabetes will be no different than that for any other American.

As an innovation-based pharmaceutical company, Lilly continues to push the boundaries of science today to bring better treatments to people with diabetes and other conditions tomorrow. Only about half the people living with diabetes and using insulin are able to fully control their condition. Increased innovation is needed to make diabetes easier to manage, and Lilly is committed to driving new innovative treatments to ease the burden of living with diabetes. For example, later this year, we expect to introduce an easier-to-use nasal glucagon treatment for life-threatening hypoglycemia. In 2018, Lilly announced its investment in a drug discovery partnership that we hope could move people with diabetes away from insulin altogether by developing cell therapies that would allow insulin-producing pancreatic beta cells to be delivered through implanted devices.<sup>22</sup> And in 2020, if approved, we expect to introduce an even faster-acting version of insulin. Lilly is also active in the space of digital health

<sup>22</sup> *Lilly and Sigilon Therapeutics Announce Strategic Collaboration to Develop Encapsulated Cell Therapies for the Treatment of Type 1 Diabetes* (Apr. 4, 2018), <https://www.prnewswire.com/news-releases/lilly-and-sigilon-therapeutics-announce-strategic-collaboration-to-develop-encapsulated-cell-therapies-for-the-treatment-of-type-1-diabetes-300624199.html>; Alex Keown, *Eli Lilly Plunks Down \$63M Upfront in Deal With Startup Sigilon* (Apr. 4, 2018), <https://www.biospace.com/article/eli-lilly-plunks-down-63m-upfront-in-deal-with-startup-sigilon>.

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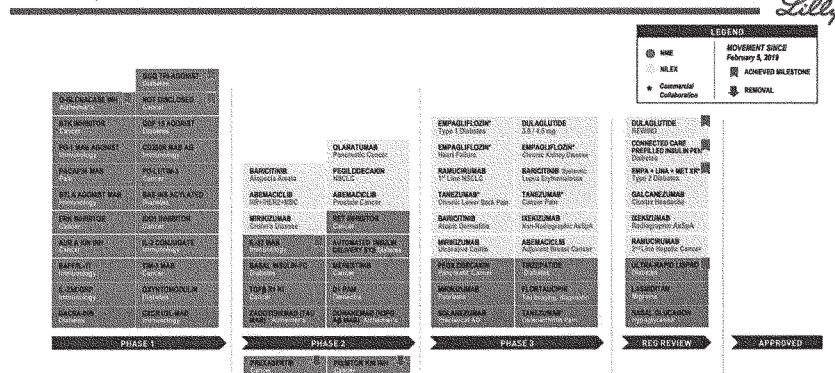
solutions and is developing a connected diabetes system consisting of devices that we hope will improve adherence, outcomes, and convenience.

Lilly is not merely an insulin manufacturer, nor is our focus limited to insulin or diabetes. In 2018 alone, Lilly spent more than \$5.3 billion on research and development, accounting for more than 20 percent of total revenues, in multiple therapeutic areas other than diabetes, including oncology, immunology, Alzheimer's disease, and chronic pain. The revenues we earn on our portfolio of products, including insulins, directly support research and development for tomorrow's life-saving medicines. Any one, or all, of our potential treatments still in development could fail during clinical trials. Indeed, risk and uncertainty are inherent to drug discovery. A recent and heartbreaking example of the risk that our company undertakes can be seen in solanezumab, a potential treatment for Alzheimer's disease that did not succeed in its last stage of clinical testing. Had it succeeded, solanezumab would have been the first disease-modifying drug to treat Alzheimer's. Nevertheless, Lilly remains committed to Alzheimer's research, and our portfolio includes other potential approaches, including a BACE inhibitor in clinical trials.

Below is a visual representation of Lilly's pipeline for new molecular entity ("NME") and indication or line extension ("NILEX") drugs.

## LILLY SELECT NME AND NILEX PIPELINE

APRIL 24, 2019



2. One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."

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**Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."**

**So, which is it? Are there patents preventing innovation and competition or not?**

We do not believe OptumRx was talking about Lilly.<sup>23</sup> No patents prohibit competitors from launching products similar to Lilly insulins. In fact, none of our insulin active ingredients are currently protected by patents. Additionally, although Lilly has filed or holds patents on certain delivery systems used with some of our insulins (e.g., U.S. Patent Number 7291132 covering "medication dispensing apparatus with triple screw threads for mechanical advantage"), this is not a barrier to insulins delivered in a variety of other ways. In fact, Sanofi launched a follow-on insulin lispro product to compete with Humalog in April 2018, and no patent litigation or other regulatory impediment inhibited Sanofi's launch of its product. The general absence of patents covering Lilly insulins is verifiable in the FDA Orange Book, which is available and searchable on the FDA's website at <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>.

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<sup>23</sup> OptumRx's written testimony from the April 10, 2019 hearing before the House Energy & Commerce Committee cites a study on Lantus, an insulin manufactured by Sanofi. <https://docs.house.gov/meetings/IF/IF02/20190410/109299/HHRG-116-IF02-Wstate-DuttaS-20190410.pdf>.

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Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Hearing on  
“Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin”

April 10, 2019

Mr. Doug Langa, Executive Vice President, North America Operations,  
President, Novo Nordisk Inc.

The Honorable Joseph P. Kennedy III (D-MA)

1. At the Oversight Subcommittee hearing on April 2, 2019, the witnesses spoke about the ineffectiveness of patient assistance programs and testified the programs are untimely, unworkable, and a barrier to accessing insulin. Whether the programs' criteria are too difficult to find or the application processes require already sick people to jump through hoops, there is wide consensus the programs are a cruel substitute for lower list prices.

Regarding patient assistance programs specifically for insulin at your company, please provide a clearer picture of how they operate by answering the following questions.

- a. Where can patients find information on eligibility and criteria for the programs?

**Answer:** There are many ways patients can access details on Novo Nordisk's patient assistance programs in order to increase the likelihood that they can obtain the information they need in a timely manner. Information about Novo Nordisk's Diabetes Patient Assistance Program (Diabetes PAP) can be found on the Novo Nordisk Patient Affordability and Access Support website-[www.NovoCare.com](http://www.NovoCare.com), as well as Novomedlink (found at [www.Novomedlink.com](http://www.Novomedlink.com)), which is directed towards healthcare providers. The NovoCare® site is also linked to Novo Nordisk U.S. diabetes branded and unbranded sites directed at healthcare providers and patients. In addition, multiple key consumer and patient-advocacy maintained sites, and related mobile applications, connect to NovoCare®, including the American Diabetes Association (ADA), American Association of Diabetes Educators (AADE), Needymeds, Inc., [medicineassistancetool.org](http://medicineassistancetool.org) (managed by PhRMA), and [Drugs.com](http://Drugs.com). Patients may also gather information through their medical providers, or by calling the Novo Nordisk Customer Care Line (at 1-800-727-6500), or the Novo Nordisk Reimbursement Hotline (at 1-855-253-2414).

- b. What are the eligibility criteria for the programs?

**Answer:** The eligibility requirements for the Diabetes PAP are as follows: The patient must be a U.S. citizen or legal resident, and must be uninsured and ineligible for Department of Veterans Affairs prescription benefits, or any federal, state, or local program such as Medicare or Medicaid. There is an exception for patients with Medicare Part D coverage who meet the threshold out-of-

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pocket spend on prescription medication, which is currently \$1,000; patients who are Medicare eligible and do not have Medicare Part D coverage and have applied for and been denied the Extra Help/Low Income Subsidy (LIS); and patients who are Medicaid eligible and have applied for and been denied Medicaid. Finally, patients need to demonstrate that their income is at or below 400% of the federal poverty level—about \$103,000 for a family of four and \$49,960 for an individual. Although these criteria govern eligibility for the Diabetes PAP, Novo Nordisk also considers patients who exceed the income threshold in certain situations—for example, job loss or sudden financial hardship—on a case-by-case basis.

- c. What information and documents must patients submit in order to qualify for the programs?

**Answer:** Patients must fill out one page of the Diabetes PAP application that seeks basic identifying information such as their name, address, and social security number, as well as information about their prescription drug coverage. Patients can provide proof of income by submitting copies of any of the following: two most current paycheck stubs or earning statements for all working members of the household; a federal income tax return from the prior year; Social Security, pension, or other income statements; W-2 or 1099 forms; or unemployment benefit statements. If applicable, patients must provide a Medicaid eligibility form or, for Medicare Part D patients, documentation (such as a letter from a provider, a statement or explanation of benefits, or a pharmacy printout) showing that the patient has spent \$1,000 on prescription medicine for the relevant benefit year. It ordinarily takes seven to ten days from the time Novo Nordisk receives a completed application until products are sent to the patient's healthcare provider. In many cases, medicine is sent to patients in less time.

- d. What number of patients apply for the programs each year, what number are approved, and what number are denied?

**Answer:** For the Diabetes PAP, Novo Nordisk received 74,713 applications in 2018 for 105,220 products, as some applications requested multiple products. 16,477 (16%) of these product applications were either withdrawn or incomplete. Among the 88,743 completed product applications, 65,077 (73%), were approved while 23,666 (27%) were denied.

- e. What are the ten most common reasons your company denies a patient's application?

**Answer:** Eligibility for Novo Nordisk's Diabetes PAP is governed by the criteria described above. If a patient does not meet those criteria, her application will not be approved. (As noted above, however, Novo Nordisk does make exceptions to the income criteria in certain situations decided on a case-by-case basis). In addition, if a patient does not complete the application process, including by verifying income eligibility, her application will not be approved.

Of the applications for the Diabetes PAP that are denied, about 70% are denied because the patient has insurance. A far less common reason is that the patient exceeds the income threshold, which occurs in 7%-20% of denials (varies by product). Other reasons include failure to meet the requirements for qualification with Medicare coverage (such as providing proof of out-of-pocket expenses) or failure to provide identifying information requested in the application (such as social

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security number or healthcare provider information). If a patient appears to be eligible for Medicaid, Novo Nordisk requires that the patient apply for Medicaid before approving their PAP application.

- f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

**Answer:** For uninsured patients, an approved application is valid for 12 months. For Medicare Part D patients, an approved application is valid for the calendar year in which they applied. Patients may be reapproved annually for as long as they meet the eligibility criteria.

- g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018?

**Answer:** Novo Nordisk invests in website design features that offer information about affordability options, including the Diabetes PAP, and has worked to improve those features each year. In addition, Novo Nordisk telephone representatives are equipped to answer questions about the Diabetes PAP when patients call the customer care line. Novo Nordisk sales representatives also educate physicians on the Diabetes PAP so that they may in turn educate patients needing assistance. Novo Nordisk works with patient organizations, such as the American Diabetes Association, to ensure that patients are aware of the affordability options available to them, including the Diabetes PAP. Because these efforts are adjunct to Novo Nordisk's general product promotion activities, it is not possible to quantify the dollars spent specifically on public awareness for the Diabetes PAP.

- i. How much did your company spend on advertising for insulin in 2018?

**Answer:** Novo Nordisk spent \$91.6 million on print and television advertising, as well as other consumer-facing marketing activities, for insulin medicines in 2018.

2. Regarding patient assistance programs at your company for all types of medication, please provide a clearer picture of how they operate by answering the following questions.

- a. Where can patients find information on eligibility and criteria for the programs?

**Answer:** In addition to the Diabetes PAP, Novo Nordisk operates Patient Assistance Programs for growth hormone disorders (Growth Hormone Patient Access Program or Growth Hormone PAP), Hemophilia (Hemophilia Product Assistance Program or Hemophilia PAP), and hormone therapy (Hormone Therapy Patient Assistance Program or Hormone Therapy PAP). Information about those programs can be found on Novo Nordisk's website [Novonordisk.us](http://Novonordisk.us), as well as other web sources, and through health care providers.

- b. What are the eligibility criteria for the programs?

**Answer:** For the Growth Hormone Patient Access Program, the following eligibility criteria apply: The patient must be a U.S. citizen or legal resident and must have a diagnosis that is an FDA-

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approved indication for Norditropin®; the patient's total household income must be at or below 350% of the federal poverty level after inclusion of Norditropin® estimated cost deduction; and the patient cannot have or qualify for government insurance, including any federal, state, or local program such as Medicare or Medicaid. Patients who are eligible for Medicaid or VA prescription benefits must have been denied enrollment, including exhaustion of all appeals, in order to be eligible for the PAP. If the patient is Medicare eligible but does not have Medicare Part D coverage, the patient must have applied for and been denied the LIS.

For the Hemophilia Product Assistance Program, the following eligibility criteria apply: The Patient must be a U.S. citizen or legal resident and must be prescribed a Novo Nordisk factor product for an indicated condition; the patient must not have prescription coverage; and the patient's total household income must be at or below 400% of the federal poverty level. The patient cannot have or qualify for government insurance, including any federal, state, or local program, such as Medicare or Medicaid, and patients who are eligible for Medicaid or VA prescription benefits must have been denied enrollment, including exhaustion of all appeals, in order to be eligible for the PAP. If the patient is Medicare eligible but does not have Medicare Part D coverage, the patient must have applied for and been denied the LIS.

For the Hormone Therapy PAP, the following eligibility criteria apply: The patient must be a U.S. citizen or legal resident; the patient must not have private prescription coverage or state, federal, or local prescription coverage, such as Medicare, Medicaid, or VA benefits; and the patient's total household income must be at or below 200% of the federal poverty level. If approved, a 90-day supply is sent to the patient's health care provider.

- c. What information and documents must patients submit in order to qualify for the programs?

**Answer:** For the Growth Hormone Therapy PAP and the Hemophilia PAP, patients must fill out the application form and provide certain documentation. For proof of income, they may provide any of the following: the two most current paycheck stubs or earning statements for all working members of the household; a copy of last year's federal income tax return (1040); a copy of Social Security income, pension, and other income statements, including interest or dividend statements; a copy of last year's (or most current) W-2 or 1099 form; or a copy of an unemployment benefits statement. Some patients must also provide a Medicaid, VA, or Extra Help/LIS denial letter (dated within 1 year of applying for the PAP). For the Growth Hormone Therapy PAP, some patients must provide a copy of their medical and pharmacy insurance cards. For the Hemophilia PAP, patients must provide their prescription with exact quantity and assay limits.

For the Hormone Replacement Therapy PAP, patients may demonstrate their income eligibility by providing their most recent federal tax return (1040), or Social Security income, Pensions, Interest, Retirement, and Child Support documentation.

- d. What number of patients apply for the programs each year, what number are approved, and what number are denied?

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**Answer:** In 2018, for the Growth Hormone Therapy PAP, Novo Nordisk received 994 applications and approved 687. Of the applications that were not approved, 221 were withdrawn or incomplete. For the Hemophilia PAP (again, in 2018), Novo Nordisk received 28 applications and approved 7. Of the remaining applications, 6 were withdrawn or incomplete. For the Hormone Therapy PAP (also in 2018), Novo Nordisk received 63 applications and approved 39.

e. What are the ten most common reasons your company denies a patient's application?

**Answer:** As described above, each of Novo Nordisk's PAPs have eligibility criteria. If patients do not meet the eligibility criteria, including by verifying income, their applications may be denied. However, Novo Nordisk evaluates certain atypical financial situations on a case-by-case basis.

The most common reason that patients are denied approval for the Growth Hormone, Hormone Therapy, and Hemophilia PAPs is that their income exceeds the eligibility threshold. Other reasons include failing to meet other criteria or providing incomplete information or documentation.

f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

**Answer:** Approvals must be renewed annually. Patients may reapply as long as they remain eligible.

g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018?

**Answer:** As explained in response to question 1, it is not possible to quantify the amount spent on public awareness campaigns for the Patient Assistance Programs because those efforts are adjunct to other corporate communications and product promotion activities.

h. How much did your company spend on advertising for medication in 2018?

**Answer:** In 2018, Novo Nordisk spent \$274 million on print and television advertising, as well as other consumer-facing marketing activities, across all of its products.

3. Are there any medications not on your company's patient assistance program? Please provide a list of the drugs that are available for patient assistance and those that are not a part of patient assistance programs.

**Answer:** All of Novo Nordisk's medicines that are currently marketed are available through Novo Nordisk's PAPs, with one exception. Saxenda®, which is used to treat obesity, is not available. Novo Nordisk considers obesity to be a separate disease space from diabetes and does not currently have an Obesity PAP.

4. Does your company make medication available to patients for free or reduced prices, or does it use a private foundation or other third parties to operate patient assistance programs? When

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your company makes contributions of medication to private foundations, such as Sanofi's Patient Connection, Sanofi's Foundation for North America, Novo Nordisk's NovoCare, Eli Lilly's Lilly Cares, or other third parties, does your company correspondingly reduce its tax liability? Please provide the amount by which your company reduced its tax liability for 2018 as a result of making contributions to patient assistance programs.

**Answer:** Novo Nordisk does not use a private foundation to operate the Patient Assistance Programs described above. The company does not take a charitable tax deduction for the products it provides to patients through its PAPs, or for costs of administering the programs. NovoCare® is not a private foundation—it is an arm of Novo Nordisk dedicated to patient access and affordability support in the U.S.

**The Honorable Brett Guthrie (R-KY)**

1. There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer decides to lower the list price of the medicine. Has Novo Nordisk received a letter from any PBMs or insurers requesting that it provide the PBM or insurer with notice before Novo Nordisk lowers the list price of insulin or any other medicine? If so, please list the entities that have sent such a letter to Novo Nordisk and describe the requirements set forth in the letter.

**Answer:** Novo Nordisk received the letter from OptumRx requesting notice of any decision to lower list prices. Novo Nordisk did not agree to provide that information. Novo Nordisk is not aware of receiving similar letters from any other PBM.

- a. Does Novo Nordisk have any contractual obligations to provide a supply chain partner with notice before lowering the list price of insulin or any other medicine? If so, please list the entities and describe the contractual provisions.

**Answer:** No. As described above, OptumRx sought to include such obligations in its contracts with Novo Nordisk, but Novo Nordisk declined.

- b. Has Novo Nordisk provided any of its supply chain partners with notice of a list price decrease? If so, please describe these interactions.

**Answer:** No, it has not.

- c. What happens to Novo Nordisk's rebate obligations with PBMs if Novo Nordisk lowers the list price of insulin or any other medicine?

**Answer:** Novo Nordisk's contracts with PBMs hold the company to a certain rebate amount. That amount is expressed as a percentage of list price. Because rebates are a function of list price, if Novo Nordisk lowers list prices for its medicines, the amount of the rebate paid to the PBM will decrease. As such, PBMs will earn less in rebates for products where the list price is lowered.

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- d. Has the letter sent by OptumRx or any other similar requests by supply chain partners impacted Novo Nordisk's decisions regarding whether to lower the list price of insulin or any other medicine? If so, please describe.

**Answer:** Although Novo Nordisk did not agree to OptumRx's request, the letter indicates the importance of rebates to the PBMs, payers, and plan sponsors. Rebates are critically important to PBMs and other payers and can represent millions of dollars for a single contract in a single year. The role and importance of rebates to payers' business models is, of course, a consideration in pricing. Novo Nordisk always considers the entire market when setting list prices, including the rebate percentages and dollars that are required to secure and maintain formulary access.

2. We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. For example, in Novo Nordisk's testimony, Novo Nordisk said that the net prices for its insulins have declined year-over-year from 2015 through 2018—the net price of the NovoLog® declined by 21 percent from 2003 to 2018 while the list price of the product increased by 310 percent during the same period. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many PBMs that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price. Please explain.

**Answer:** As outlined above, rebates are critically important to PBMs and other payers and can represent millions of dollars for a single contract in a single year. Novo Nordisk has had discussions with payers about the possibility of eliminating rebates and focusing instead on net price—in other words, lowering list price to the amount the company actually receives from payers. In those discussions, PBMs and other payers have expressed concern about the consequences of such a systemic change and have been unwilling to offer assurances that Novo Nordisk would maintain its formulary positions if it no longer offered rebates.<sup>1</sup>

Formulary access is crucial to ensuring that Novo Nordisk's products reach the patients who rely on them. Having products available on formulary is the way that the vast majority of patients can access Novo Nordisk products at reasonable co-pays. If Novo Nordisk products were excluded from formularies, patients would either have to pay much higher prices for their medicine or switch to another product that might not work as well for them. No two diabetes patients are alike, which is why it is so important that patients not lose access to the medicines that work for them.

Because of consolidation, the three PBMs who testified at the April 10<sup>th</sup> hearing manage the pharmacy benefit for over 80% of the patients in the United States. Accordingly, losing access to any of their formularies would materially impact Novo Nordisk's business and market share,

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<sup>1</sup> The question correctly notes that there has been a decline in the net price of NovoLog® since 2003. It is important to recognize that the 21% decline reflects adjustments for inflation.

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as well as Novo Nordisk's ability to deliver its medicines to patients. For these reasons, in the current system, Novo Nordisk must proceed cautiously with respect to reducing or eliminating rebates. Complicating matters, rebate pressures have been increasing year over year. Across all products and channels, Novo Nordisk paid 68% in rebates and other discounts and fees last year—up 40% from 2014. As long as this persists, Novo Nordisk must offset growing rebate demands with list price increases in order to remain a sustainable business capable of delivering its medicine to patients and continuing to invest in innovation to ultimately defeat diabetes.

Novo Nordisk supports the proposed rule from the Department of Health and Human Services, *Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees* (the Rebate Rule). Novo Nordisk believes that the Rebate Rule will benefit patients and supports its expansion to the commercial market. However, Novo Nordisk believes that the wholesale conversion of both markets simultaneously could cause confusion in the marketplace and disrupt patient access to medications. There are many new operational and system requirements necessary to ensure that the appropriate discount is applied at the pharmacy counter, that patient cost-sharing responsibilities are correctly calculated, and that pharmacies are fully compensated. Previous changes of this magnitude have been afforded years for implementation, and were themselves not without challenges at the outset. Therefore, Novo Nordisk supports a focus on ensuring a successful implementation in the Part D market before moving on to other channels.

Novo Nordisk also supports other legislative or regulatory changes that would ensure that the rebates pharmaceutical manufacturers pay to secure and maintain formulary access are passed on to the patients who use those medicines.

3. Are any of Novo Nordisk's insulin drug substances currently protected by patents or are all of the current patent protections on Novo Nordisk's insulin products for the delivery systems? Please describe how a patent on the delivery system limits the ability of a competitor to make a generic version of the product.

**Answer:** Several of Novo Nordisk's insulin drug substances are protected by patents, while several are not. Novo Nordisk also manufactures devices, which are the result of significant innovation and are also protected by patents. These devices allow for more accurate and convenient delivery of insulin, allowing patients to dose themselves more easily and with less pain. They also allow patients who may struggle with fine motor skills to self-dose, thereby obviating the need for medical assistance and permitting patients—particularly elderly patients—to maintain their independence.

Patents on Novo Nordisk's innovative devices do not impede the ability of generic competitors to produce the underlying medication. A generic competitor may produce the unpatented substance and market it in their own delivery device, or for use with a traditional vial and syringe.

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4. During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are oftentimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.
  - a. What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?

**Answer:** The disadvantage of a system in which administrative fees are paid as a percentage of list price is that there is increased pressure to keep list prices high because various actors in the supply chain benefit from the higher prices. This is an example of misaligned incentives in the current system.

- b. Does your company support moving to a system where administrative fees are based on a flat fee instead?

**Answer:** Novo Nordisk supports moving to a flat fee system, provided that the fees are based on the fair market value of the service rendered. Novo Nordisk agrees with the position taken in the proposed Rebate Rule that such fees cannot be determined based on additional business that is provided to the PBM or health plan by manufacturers.

**The Honorable Jeff Duncan (R-SC)**

1. One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba® and Fiasp® and have also created new, more accurate and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.

Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and 'manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents.'"

So, which is it? Is there innovation in the insulin market or not?

**Answer:** The suggestion that insulin has not changed in 100 years is incorrect. In fact, there has been significant innovation over the last several decades with continued research and development in the insulin space occurring even in these most recent years.

During the mid-20th century, advances in insulin purification and stability allowed many patients to dose insulin more safely and accurately. In the 1980s, advances in the use of recombinant DNA

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technology meant that patients requiring insulin would no longer have to depend on bovine or porcine sources in order to control their glucose levels. Human insulin revolutionized the treatment of diabetes because it could be produced in a purer form, and it reduced the occurrence of allergic reactions.

The development of analog insulins in 2000 represented another significant change in diabetes therapies. Novo Nordisk's analog insulin, sold under the name NovoLog®, is a modified form of human insulin in which the amino acid structure of the insulin molecule has been altered at specific sites to change the onset and duration. For patients, this provides better control of mealtime blood glucose levels by more closely matching the body's natural insulin action. In doing so, the medication allows for a more flexible lifestyle, as injections can be taken immediately before, or even just after, meals. This flexibility offers a meaningful improvement in quality of life for patients as well as improvements in their glucose levels immediately following a meal.

In just the last five years, Novo Nordisk has introduced other new products that materially improve patients' lives. In 2015, Novo Nordisk introduced Tresiba®, a long-acting basal insulin, offering once daily dosing at any time of day for both type 1 and type 2 diabetes patients.<sup>2</sup> This medication's unique mechanism of action allows for improved blood sugar control with a lower risk for nighttime hypoglycemia as compared to other basal insulins. In addition to its standard concentration, Tresiba® is available in a more concentrated formula for those patients who require higher doses of insulin, allowing them to take a single dose per day with a pen device. Even more recently, in 2017, Novo Nordisk introduced Fiasp®, a new short-acting insulin that offers quicker onset when compared to other current analog insulins. These two recent advances, Tresiba® and Fiasp®, have allowed people who are insulin-dependent to safely and effectively control their diabetes around mealtimes, when blood sugar rises quickly after eating, as well as overnight and in-between meals. For patients, better nighttime control may mean the difference between getting a good night's sleep and waking for a productive day ahead, and experiencing the very frightening and often times dangerous sleep interruptions caused by fluctuations in glucose levels through the night.

Today, Novo Nordisk is the largest private funder of diabetes research and development in the world. Novo Nordisk has also formed research collaborations to further innovation in diabetes, including one with the Massachusetts Institute of Technology to develop a capsule device that contains compressed insulin, which is injected into the patient after the capsule reaches the stomach. This capsule could potentially replace insulin injections through pens or syringes, making it easier for patients to receive their medication. Novo Nordisk is also conducting research into stem cell therapies to treat diabetes in collaboration with the University of California, San Francisco, as well as other chronic diseases.

These developments in diabetes care and treatment demonstrate Novo Nordisk's commitment to improving patients' lives through new medications and delivery systems. Novo Nordisk will continue to innovate to address the needs of patients and to meet the goal of defeating diabetes.

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<sup>2</sup> At the hearing, Chair DeGette suggested in a closing statement that Tresiba® is not an insulin, but is a product that is used to improve insulin absorption in patients with type 2 diabetes. See Tr. at 140. It is important to clarify that this is incorrect – Tresiba® is an insulin medicine and is FDA approved for patients with both type 1 and type 2 diabetes.

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The assertion that there is no competition in the insulin market is also incorrect. As a single company, Novo Nordisk pays approximately 10% of all rebates across the entire pharmaceutical industry, much of that within the insulin space. This is a result of the fierce competition between the insulin manufacturers, in the current system, to secure and maintain formulary access. In 2018 alone, Novo Nordisk invested approximately \$18 billion in rebates, discounts, and other fees. The company makes this investment to ensure that patients who rely on Novo Nordisk's medicines can continue to access them at reasonable co-pays.

2. One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."

Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

So, which is it? Are there patents preventing innovation and competition or not?

**Answer:** As outlined above, there is significant competition in the insulin market, as evidenced by the degree to which rebates to secure formulary access grow each year.

With respect to generic alternatives, Novo Nordisk cannot speak to the reasons why a generic competitor has not brought a product to market. This could be because insulin products, as large peptide biologics, are more difficult to produce than some other prescription medicines for a variety of reasons. Nonetheless, Novo Nordisk supports competition in the insulin market. Several of Novo Nordisk's medicines are no longer covered by patents and, if a generic competitor attempted to produce a generic alternative to those products, Novo Nordisk would not prevent them from doing so (assuming the product met applicable FDA requirements).

PRIVILEGED AND CONFIDENTIAL  
DRAFT OF 6/7/2019

Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Hearing on  
“Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin”

April 10, 2019

Ms. Kathleen Tregoning, Executive Vice President for External Affairs, Sanofi

The Honorable Joseph P. Kennedy III (D-MA)

1. At the Oversight Subcommittee hearing on April 2, 2019, the witnesses spoke about the ineffectiveness of patient assistance programs and testified the programs are untimely, unworkable, and a barrier to accessing insulin. Whether the programs' criteria are too difficult to find or the application processes require already sick people to jump through hoops, there is wide consensus the programs are a cruel substitute for lower list prices.

Regarding patient assistance programs specifically for insulin at your company, please provide a clearer picture of how they operate by answering the following questions.

Sanofi has adopted a variety of approaches to work within the current system to improve access and affordability of insulin for patients. We have developed some of the most forward-leaning programs to help patients afford Sanofi's insulin products. We have three primary patient support programs that are designed to improve patient access to, and affordability of, Sanofi insulins.<sup>1</sup> In addition, Sanofi has various other patient support programs that provide patient access and assistance for our non-insulin products. We have developed these programs to address affordability challenges patients face due to the different circumstances they face, including insurance status, formulary design, and the increased prevalence of high deductible health plans. Each program is tailored to a specific population and designed to help address a different problem. Despite the many challenges and perverse incentives that exist in our health care system, Sanofi's commitment to patient affordability means that, today, approximately 75 percent of all patients taking Sanofi insulin pay less than \$50 per month.

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<sup>1</sup> Additionally, Sanofi offers the eVoucherRX Program to patients who manage their diabetes with Apidra/Apidra SoloSTAR, Lantus/Lantus SoloSTAR, Toujeo SoloSTAR/Toujeo Max Solostar, or Soliqua 100/33. The purpose of the eVoucherRX Program is to provide commercially insured patients with financial support through pharmacies participating in the program. The program is a co-pay assistance program applied automatically at the pharmacy counter without any enrollment process. The program reduces these patients' out-of-pocket costs to \$0 with a maximum benefit of \$1500 per year. The third-party vendor that administers the program screens claim submissions to mitigate the risk that the program could be used by federal health care program beneficiaries, consistent with OIG guidance.

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Federal beneficiaries, including beneficiaries enrolled in Medicare and Medicaid, do not have access to some of our patient assistance programs. We support changing the law to allow co-pay assistance to be provided to federal program beneficiaries.

Our patient support programs for insulins and other products are described below.

- **Sanofi Co-pay Assistance Programs:** Sanofi has co-pay assistance programs for insulins and for other Sanofi products. Sanofi co-pay assistance programs aim to lower out-of-pocket costs for commercially insured patients regardless of income level.

Patients are able to register and download electronic co-pay cards from a Sanofi website, or may contact our call center at (855) 984-6302 to request an actual co-pay card. Patients also may receive actual co-pay cards from their healthcare providers. Consistent with prior OIG guidance regarding the application of the federal Anti-Kickback Statute to coupon programs for federal beneficiaries,<sup>2</sup> Sanofi does not make its co-pay card programs available to patients covered by federal healthcare programs. In addition, and also consistent with OIG recommendations, Sanofi co-pay cards must be activated prior to use through an online activation process or by calling a call center number specified on the card. Patients who apply for Sanofi co-pay assistance may be approved that same day.

- **Insulins Valyou Savings Program:** In early 2018, Sanofi launched the Insulins Valyou Savings Program to provide financial relief to uninsured and cash paying patients. The program enabled eligible patients to access Sanofi insulins for \$99 per 10 mL vial or \$149 for a pack of SoloSTAR pens, which was approximately a 60% discount below the list price; this could result in savings of up to \$3,000 per year.<sup>3</sup>

In April, Sanofi announced an expansion of the Valyou Savings program. Effective June 8, we will transition the program to a monthly 'Netflix'-like subscription model so that uninsured patients exposed to high out-of-pocket costs at the pharmacy counter will be able to access any combination of Sanofi insulin (with the exception of Soliqua) for a fixed price of \$99/month for up to 10 vials or packs of SoloSTAR pens. Under the

<sup>2</sup> See <https://www.oig.hhs.gov/compliance/alerts/bulletins/index.asp> (May 2014).

<sup>3</sup> Patients with type 1 diabetes require insulin replacement with both background (basal) and mealtime (bolus) insulin. An average adult with type 1 diabetes who weighs 70 kg (155 pounds) should be taking anywhere from 0.5-1 u/kg/day - depending upon activity levels, and meal choices. If a higher daily dose of 1 u/kg/day is used, the patient would need a total of 70 units/day of insulin, of which ~ half should be mealtime bolus insulin and half should be background basal insulin. That would mean the patient could possibly manage her disease with one vial of long acting and one vial of short acting or a pen pack for basal and bolus each month. For the average patient with type 1 diabetes, under the Valyou program, the patient would meet the monthly insulin requirement with two payments of \$99.

For patients with type 2 diabetes, many require background (basal) insulin only. Our internal data show that the average daily dose is roughly 45 units per day which results in a monthly requirement of 1350 units of basal insulin per month. The Lantus SoloSTAR pack contains 1500 units of insulin (5 pens x 300 units per pen) and the Toujeo SoloSTAR pack contains 1350 units of insulin (3 pens x 450 units per pen). For the average patient with type 2 diabetes, under the Valyou program, the patient would meet the monthly insulin requirement with one payment of \$149. Patients on lower doses of Lantus per month could opt for the 10ml vial, which is \$99 per vial.

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Valyou Savings Program, prices are guaranteed for 12 consecutive monthly fills. The program is available through all U.S. pharmacies and there are **no income** requirements.

Patients are able to register and download an electronic savings card from a Sanofi website (<https://www.admelog.com/insulins-valyou-savings-program/>), or may contact Sanofi's call center at (855) 984-6302 to request the savings card. Patients also may receive savings cards from their healthcare providers. Consistent with the analysis contained in an OIG advisory opinion on programs that allow patients to access drugs outside of their insurance at a cash price,<sup>4</sup> Sanofi does not make the Valyou Savings Program available to federal healthcare program beneficiaries. In addition, consistent with OIG recommendations, patients must activate the savings cards prior to use through an online process or by calling a call center number specified on the card. Patients who meet eligibility criteria are immediately approved for the Insulins Valyou Savings Program and may be used the same day.

- **Sanofi Patient Connection (SPC):** The purpose of Sanofi Patient Connection (<http://www.sanofipatientconnection.com/>) is to administer Sanofi's patient assistance program, which provides financially needy patients who meet eligibility criteria with free medicine. The Sanofi Patient Connection application is available online<sup>5</sup> or by calling Sanofi Patient Connection and Patients who apply for Sanofi Patient Connection are approved, on average, within two to five business days.
- **Additional Sanofi Patient Assistance Programs:** In addition to the SPC, Sanofi provides other medicines within its portfolio free of charge to eligible patients through other patient assistance programs. The purpose of all Sanofi free drug patient assistance programs is to provide financially needy patients who meet the eligibility criteria with free medications.

In addition to the programs outlined above, Sanofi continues to work with policy-makers on initiatives that would remove the existing barriers to patient access and affordability, including removing the restrictions on providing co-pay assistance to Medicare Part D beneficiaries.

**a. Where can patients find information on eligibility and criteria for the programs?**

Sanofi makes information about its co-pay assistance programs, Insulins Valyou Savings Program, and SPC — including eligibility criteria — readily accessible to, and easily understandable for, patients. Sanofi publishes information about its patient support programs in a variety of forums, including on the Internet, through social media, through direct outreach to physicians, pharmacies and advocacy organizations (including those focused on diabetes awareness and education), in direct-to-consumer advertising, and over the phone to patients who contact the Sanofi patient support call centers.

<sup>4</sup> See OIG Advisory Opinion No. 14-05.

<sup>5</sup> See [http://www.sanofipatientconnection.com/media/pdf/SPC\\_Application.pdf](http://www.sanofipatientconnection.com/media/pdf/SPC_Application.pdf).

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With respect to information on the Internet, patients can access information about Sanofi's patient support programs, including eligibility criteria for those programs, through: (1) program-specific Sanofi websites,<sup>6</sup> (2) the Teaming Up For Diabetes website (<http://www.teamingupfordiabetes.com>), the Sanofi US website, which provides a link to each program-specific website, and (3) on Medication Assistance Tool (<https://mat.org/>), a publicly available website maintained by the Pharmaceutical Research and Manufacturers of America (PhRMA), which provides a dedicated search engine to help patients search for financial assistance resources.

**b. What are the eligibility criteria for the programs?**

Outlined below are the eligibility criteria for each of the three Sanofi patient support program described above.

**I. Sanofi Co-pay Assistance Programs for Insulin Products**

Commercially insured patients, regardless of income level, are eligible to participate in Sanofi's co-pay assistance programs. To help Sanofi determine a patient's eligibility, the patient must answer the following questions:

- Are you a current resident of the United States, Puerto Rico, Guam, or the US Virgin Islands?
- Are you a patient or caregiver over 18 years old?
- Do you have private commercial health insurance?
- Do you currently receive Medicaid?
- Are you currently serving in the US military?
- Do you qualify for Medicare?

Based on the answers to these questions, Sanofi's vendor determines eligibility.

The Sanofi co-pay cards may not be used for prescriptions that are covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or other federal or state programs, including any state pharmaceutical reimbursement program. This restriction is in place to comply with OIG guidance relating to the Anti-Kickback Statute — namely that pharmaceutical manufacturers may not offer co-pay assistance to federal program beneficiaries.

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<sup>6</sup> For eligibility and criteria information relating to Sanofi's Rx Savings Program for Lantus, patients can visit <https://www.lantus.com/sign-up/savings-and-support>. For eligibility and criteria information relating to Sanofi's Rx Savings Program for Toujeo, patients can visit <https://www.toujeo.com/toujeo-savings-card-coupon-and-support>. For eligibility and criteria information relating to Sanofi's Apidra \$0 Co-Pay Program, patients can visit <https://www.apidra.com/apidra/saving.aspx>. For eligibility and criteria information relating to Sanofi's Soliqua 100/33 Savings Card, a patient can visit <https://www.soliqua100-33.com/savings-and-support>. For eligibility and criteria information relating to the Sanofi Valyou Savings Program, patients can visit <https://www.admelog.com/insulins-valyou-savings-program/>. For eligibility and criteria information relating to Sanofi's provision of free medicines through Sanofi Patient Connection, patients can visit Sanofi Patient Connection, <http://www.sanofipatientconnection.com/patient-assistance-connection>.

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Sanofi supports policy reforms that would remove these restrictions, which would help to make insulins and other products more accessible and affordable to patients in federal programs.

## II. Sanofi Insulins Valyou Savings Program

Uninsured and cash paying patients, regardless of income level, are eligible to participate in the Insulins Valyou Savings Program. Similar to the Sanofi co-pay assistance programs, to help determine a patient's eligibility for the Sanofi Insulins Valyou Savings Program, the patient must answer the following questions:

- Are you a current resident of the United States, Puerto Rico, Guam, or the US Virgin Islands?
- Are you a patient or caregiver over 18 years old?
- Do you have private commercial health insurance?
- Do you currently receive Medicaid?
- Are you currently serving in the US military?
- Do you qualify for Medicare?

Based on the answers to these questions, Sanofi's vendor determines eligibility.

Consistent with the OIG guidance explained above, as well as an advisory opinion from OIG concerning direct-to-patient cash price programs,<sup>7</sup> the Insulins Valyou Savings Program is not available to federal program beneficiaries, such as Medicare patients. Sanofi supports policy reforms that would remove these restrictions, so that we could extend the Valyou Savings Program to Medicare and other federally insured patients.

## III. Sanofi Patient Connection

To be eligible for our patient assistance program through Sanofi Patient Connection, a patient must meet the following criteria:

- The patient must be a U.S. citizen or resident and be under the care of a licensed healthcare provider authorized to prescribe, dispense and administer medicine in the U.S.;
- The patient must also have:
  - No insurance coverage or access to the prescribed product or treatment via their insurance; or
  - Medicare Part D coverage and 1) not have coverage for a generic equivalent product and 2) have spent at least 5% of their annual household income on prescription medications covered through their Part D plan in the current year; and

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<sup>7</sup> See OIG Advisory Opinion No. 14-05.

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- o In each instance, an annual household income of  $\leq 250\%$  of the current Federal Poverty Level (for example, in 2019, \$64,375 for a family of 4).

Patients potentially eligible for Medicaid are required to provide documentation of a Medicaid denial before they may be eligible for patient assistance through Sanofi Patient Connection.

**c. What information and documents must patients submit in order to qualify for the programs?**

The product and program-specific websites referenced in footnote 6 above outline the documents and information that patients must submit to qualify for a Sanofi patient support program.<sup>8</sup> A more general description follows for ease of reference.

I. Sanofi Co-pay Assistance Programs for Insulin Products and Insulins *Valyou* Savings Program

To qualify for Sanofi's insulin co-pay assistance programs and Insulins *Valyou* Savings Program, a patient must provide his or her name, email address, and date of birth on the enrollment form. The patient also must certify that he or she meets all eligibility criteria. If the patient meets the criteria, the patient may access the program.

II. Sanofi Patient Connection

To qualify for free medicine through Sanofi Patient Connection, a patient and/or the patient's physician must complete an application, which can be submitted online, by fax, or through U.S. mail. The application requires, in part: the patient's HIPAA authorization for the release of the patient's identification and insurance information to Sanofi and their agents and representatives for benefit verification; information relating to the patient's prescription, including dosage and the diagnosis code; the state license number and signature of the prescriber; the patient's household income verification and authorization to run a soft credit inquiry/background check; and the patient's signature. The patient must also provide his or her own identifying information, including name, address, date of birth, social security number, and health insurance information, and identifying information for the prescriber.

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<sup>8</sup> See *infra* Footnote 6.

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**d. What number of patients apply for the programs each year, what number are approved, and what number are denied?**

The chart below outlines the estimated<sup>9</sup> number of patients that applied for, were approved, and were denied for Sanofi's insulin-related patient support programs during the 2018 calendar year:

<b>Program</b>	<b>Applications Received</b>	<b>Applications Approved<sup>10</sup></b>	<b>Applications Denied</b>
Insulin-Related Co-Pay Assistance Programs and Insulins <i>Valyou</i> Savings Program	382,000	250,841	56,000
Sanofi Patient Connection for Insulin Products	84,164	61,095	23,069

**e. What are the ten most common reasons your company denies a patient's application?**

As a business practice, Sanofi tracks the top three reasons for denials of patient support program applications for insulin products. Those three reasons for 2018 are provided below for each of the three programs.

**I. Sanofi Co-pay Assistance Programs for Insulin Products**

The top three reasons for denial of a patient's application for an insulin co-pay assistance program are:

- 1) the patient has health care coverage for the insulin product under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs;
- 2) the patient is not a resident of the US; and
- 3) the patient does have commercial insurance and has been prescribed Admelog (in which case the patient is invited to apply for the Insulins *Valyou* Savings Program).

These three reasons represent 100% of the total application denials for Sanofi's Insulin Co-pay Assistance Programs.

<sup>9</sup> Sanofi does not track or maintain data regarding the total number of applications received and denied for insulin co-pay assistance programs and the Insulins *Valyou* Savings Program. The information provided regarding the total number of applications received and denied are estimates.

<sup>10</sup> The number of applications approved for Insulin-Related Co-Pay Assistance Programs and the Insulins *Valyou* Savings Program reflects total unique patients approved for enrollment, rather than number of applications approved.

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II. Insulins Valyou Savings Program

The top three reasons for denial of a patient's application for the Insulins Valyou Savings program are:

- 1) the patient has health care coverage for the insulin product under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs;
- 2) the patient is not a resident of the US; and
- 3) the patient has commercial insurance and utilizing one of our co-pay programs would allow the patient to access their insulin at a lower out-of-pocket cost.

These three reasons represent 100% of the total application denials for the Insulins Valyou Savings Program.

III. Sanofi Patient Connection

The top three reasons for denial of a patient's application for SPC are:

- 1) the patient has insurance coverage for the product;
- 2) financial eligibility for the program has not been met; and
- 3) an off-label diagnosis code was provided.

The first two reasons mentioned above represent 94% of the total application denials. If a patient is denied, the patient is offered the opportunity to apply for the Insulins Valyou Savings Program.

**f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?**

The reapplication process for Sanofi's insulin-related patient support programs varies by program and is designed to comply with OIG guidance.

I. Sanofi Co-pay Assistance Programs for Insulin Products and Insulins Valyou Savings Program

With respect to the insulin-related co-pay assistance programs and the Insulins Valyou Savings Program, patients must reapply for approval after the patient has used the co-pay card 12 times. Sanofi requires patients to reapply for approval under a co-pay assistance program or the Insulins Valyou Savings Program to help ensure that all enrolled patients continue to meet the eligibility criteria, including eligibility criteria relating to compliance with the Anti-Kickback Statute.

II. Sanofi Patient Connection

Patients eligible for Medicare Part D must reapply for the free drug through Sanofi Patient Connection at the end of every calendar year, which aligns with OIG guidance that patient

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assistance must be available for the Medicare Part D plan year.<sup>11</sup> All other patients must reapply for approval for free drug through Sanofi Patient Connection every 12 months. Sanofi requires that patients reapply for approval every 12 months to ensure that patients' insurance status has not changed from the prior year and that they continue to meet eligibility requirements.

**g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for insulin in 2018?**

In 2018, Sanofi spent approximately \$414.87 million on advertising for insulin products, which includes direct-to-consumer advertising, direct-to-physician advertising, and promotion of co-pay assistance programs for insulin and the Insulins Valyou Savings Program through the Internet, social media, direct outreach to physicians, pharmacies and advocacy organizations (including those focused on diabetes awareness and education), and over the phone to patients who contact the Sanofi patient support call centers.

**2. Regarding patient assistance programs at your company for all types of medication, please provide a clearer picture of how they operate by answering the following questions.**

**a. Where can patients find information on eligibility and criteria for the programs?**

As with its patient support programs for insulin products, Sanofi publishes information about its patient support programs for all products in a variety of forums, including on the Internet, through social media, through direct outreach to physicians, pharmacies, and advocacy organizations, in direct-to-consumer advertising, and over the phone to patients who contact the Sanofi patient support call centers at (855) 984-6302.

**b. What are the eligibility criteria for the programs?**

**I. Sanofi Co-Pay Assistance Programs**

In addition to the co-pay assistance programs for insulin products described above, Sanofi has developed and maintains co-pay assistance programs for Aubagio, Lemtrada, Dupixent, Kevzara, Libtayo, Alprolix, Eloctate, Aldurazyme, Cerdelga, Cerezyme, Fabrazyme, Lumizyme, and Thyrogen, and Praluent. The eligibility criteria and other terms for each of the programs are outlined on the websites that describe each program.<sup>12</sup> Generally, there are two predominant

<sup>11</sup> 70 Fed. Reg. 70623, 70627 (Nov. 22, 2005).

<sup>12</sup> Eligibility criteria for the Aubagio \$0 Co-Pay Program can be found at [https://www.aubagiohcp.com/support-resources?s\\_mcid=ps-AGH-google-Branded-Information-Co-Pay](https://www.aubagiohcp.com/support-resources?s_mcid=ps-AGH-google-Branded-Information-Co-Pay). Eligibility criteria for the Lemtrada Co-Pay Program can be found at <https://www.lemtradahcp.com/patient-support>. Eligibility criteria for the Dupixent MyWay Co-Pay Card Program can be found at <https://www.dupixenthcp.com/atopicdermatitis/access-support/dupixent-myway>. Eligibility Criteria for the Kevzara Connect Copay Card can be found at <https://www.kevzarahcp.com/kevzara-connect>. Eligibility criteria for the Libtayo Surround Commercial Co-Pay Program can be found at <https://www.libtayohcp.com/accessinglibtayo/patientaccessandreimbursementsupport>. Eligibility criteria for the Alprolix Co-Pay Program can be found at <https://www.alprolix.com/resources/financial->

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eligibility criteria that are consistent across all Sanofi co-pay assistance programs: 1) commercially insured patients can participate in Sanofi's co-pay assistance programs regardless of income level; and 2) consistent with OIG guidance relating to the Anti-Kickback Statute, Sanofi co-pay assistance may not be used in connection with prescriptions that are covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs, including any state pharmaceutical program.

II. Sanofi Free Drug Patient Assistance Programs

The predominant eligibility criteria for SPC described above in response to Question 1(b) generally apply to all of Sanofi's free drug patient assistance programs, with minor differences in eligibility criteria among the various programs.

**c. What information and documents must patients submit in order to qualify for the programs?**

I. Sanofi Co-Pay Assistance Programs

The information and enrollment forms a patient must submit to qualify for Sanofi's co-pay assistance programs for its other products are similar to the information and enrollment forms described in Question 1(c) above for insulin-related co-pay assistance programs.

II. Sanofi Free Drug Patient Assistance Programs

The information requirements and enrollment process outlined in response to Question 1(c) for SPC (including for insulin products) is similar to and generally consistent with the information requirements and enrollment process applicable to the other Sanofi free drug patient assistance programs.

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[assistance.aspx](https://www.eloctate.com/resources/downloads.aspx?gclid=CjwKCAjw27jnBRBuEiwAdjQXDCWEfWNfC78ioeULgVejHZLwutiy9X7t4VrYvQSugdVZr16UDx2iMxoCkBOQAvD_BwE&gclidsrc=aw.ds). Eligibility criteria for the Elocetate Co-Pay Assistance Program can be found at [https://www.eloctate.com/resources/downloads.aspx?gclid=CjwKCAjw27jnBRBuEiwAdjQXDCWEfWNfC78ioeULgVejHZLwutiy9X7t4VrYvQSugdVZr16UDx2iMxoCkBOQAvD\\_BwE&gclidsrc=aw.ds](https://www.eloctate.com/resources/downloads.aspx?gclid=CjwKCAjw27jnBRBuEiwAdjQXDCWEfWNfC78ioeULgVejHZLwutiy9X7t4VrYvQSugdVZr16UDx2iMxoCkBOQAvD_BwE&gclidsrc=aw.ds). Eligibility criteria for the Aldurazyme Co-Pay Assistance Program can be found at <https://www.aldurazyme.com/patients/patient-services/sanofi-genzyme-co-pay-assistance-program.aspx>. Eligibility criteria for the Cerdelga Co-Pay Assistance Program can be found at <http://cerdelga.com/co-pay.html>. Eligibility criteria for the Cerezyme Co-Pay Assistance Program can be found at [https://www.cerezyme.com/patients/patient\\_services/cerezyme\\_co-pay\\_assistance\\_program.aspx](https://www.cerezyme.com/patients/patient_services/cerezyme_co-pay_assistance_program.aspx). Eligibility criteria for the Fabrazyme Co-Pay Assistance Program can be found at <https://www.fabrazyme.com/patients/Patient-Services/co-pay-assistance-program.aspx>. Eligibility criteria for the Lumizyme Co-Pay Assistance Program can be found at [https://www.lumizyme.com/patients/patient\\_services/co-pay\\_assistance\\_program\\_prequalifier.aspx](https://www.lumizyme.com/patients/patient_services/co-pay_assistance_program_prequalifier.aspx). Eligibility criteria for the Thyrogen Co-Pay Assistance Program can be found at <https://www.thyrogen.com/patients/Financial-Assistance/Financial-Assistance-Programs.aspx>.

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**d. What number of patients apply for the programs each year, what number are approved, and what number are denied?**

Across its patient support programs in 2018, Sanofi approved a large number of applications that resulted in thousands of patients having access to Sanofi products at more affordable prices. Sanofi received 106,477 applications for free drug product provided through SPC. Of those applications, Sanofi approved 67,216 applications and denied 26,652 applications (12,609 applications were cancelled by the patient or the patient's provider prior to approval or denial). Sanofi is committed to helping patients access its products.

**e. What are the ten most common reasons your company denies a patient's application?**

Please see the response to Question 1(e) above for information responsive to this question with respect to products provided through Sanofi Patient Connection. Sanofi Patient Connection includes insulins and certain other Sanofi product, but does not include certain other Sanofi products that are available through other patient assistance programs.

**f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?**

Please see the response to Question 1(f) above for information responsive to this question with respect to products provided through Sanofi Patient Connection. Sanofi Patient Connection includes insulins and certain other Sanofi product, but does not include certain other Sanofi products that are available through other patient assistance programs.

**g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for medication in 2018?**

In 2018, Sanofi spent approximately \$4.5 billion on advertising and marketing for all of its products.<sup>13</sup> Such spending is inclusive of public awareness campaigns to promote Sanofi patient support programs.

**3. Are there any medications not on your company's patient assistance program? Please provide a list of the drugs that are available for patient assistance and those that are not a part of patient assistance programs.**

Through the Valyou Savings Program, Sanofi helps to lower out-of-pocket costs for patients who manage their diabetes with the following products:

- Lantus
- Lantus SoloSTAR
- Admelog

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<sup>13</sup> "Advertising and marketing" includes global spending on promotion and marketing management.

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- Admelog SoloSTAR
- Apidra
- Apidra SoloSTAR
- Toujeo
- Toujeo SoloSTAR

Through Sanofi co-pay assistance programs, Sanofi helps to lower the out-of-pocket costs for patients who are prescribed the following products:

- Aldurazyme
- Alprolix
- Apidra
- Apidra SoloSTAR
- Aubagio
- Cablivi
- Caprelsa
- Cerdelga
- Cerezyme
- Dupixent
- Elocate
- Fabrazyme
- Kevzara
- Lantus
- Lantus SoloSTAR
- Lemtrada
- Libtayo
- Lumizyme
- Multaq
- Praluent
- Soliqua 100/33
- Thyrogen
- Toujeo
- Toujeo SoloSTAR
- Toujeo Max SoloSTAR

Sanofi provides free medicine through patient assistance programs for the following products:

- Adacel
- Admelog
- Adlyxin
- Aldurazyme
- Alprolix
- Apidra
- Aubagio

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- Cablivi
- Caprelsa
- Cerdelga
- Cerezyme
- Dupixent
- Elitek
- Elocate
- Fabrazyme
- Imogam
- Imovax
- Jevtana
- Kevzara
- Lantus
- Lemtrada
- Libtayo
- Lovenox
- Lumizyme
- Menactra
- Mozobil
- Multaq
- Pentacel
- Praluent
- Priftin
- Soliqua 100/33
- Tenvirac
- Thymoglobulin
- Thyrogen
- Toujeo
- Zaltrap<sup>14</sup>

4. **Does your company make medication available to patients for free or reduced prices, or does it use a private foundation or other third parties to operate patient assistance programs? When your company makes contributions of medication to private foundations, such as Sanofi's Patient Connection, Sanofi's Foundation for North America, Novo Nordisk's NovoCare, Eli Lilly's Lilly Cares, or other third parties, does your company correspondingly reduce its tax liability? Please provide the amount by which your company reduced its tax liability for 2018 as a result of making contributions to patient assistance programs.**

Sanofi's "Sanofi Cares North America" and "Genzyme Charitable Foundation, Inc" are 501(c)(3) organizations through which Sanofi makes its medications available free of charge to financially eligible uninsured and under-insured patients. Sanofi Cares North America provides

<sup>14</sup> Sanofi does not provide patient support for the following products: Ambien, Arava, Avalide, Avapro, Clolar, Eloxatin, Ferlecit, Hectorol, Seprafilm, Synvisc, and Taxotere.

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Sanofi products free of charge to eligible financially needy uninsured and underinsured patients through Sanofi Patient Connection. Sanofi Cares North America also donates product to five non-governmental organization partners—Americares, DirectRelief, Heart to Heart International, MAP International, and Project Hope—and to approximately one hundred summer camps with 501(c)(3) status for children with diabetes.

Under the US Internal Revenue Code, a corporation can claim a deduction for charitable contributions to qualifying organizations. The deduction is limited to 10% of the corporation's taxable income. The product donations described above qualify for that deduction and therefore reduce Sanofi's federal taxable income, subject to the limitations in the tax code. Sanofi also makes cash donations that qualify as tax deductible charitable contributions. As there is no ordering rule to distinguish between cash and product donations, it is not possible to determine exactly how much of the 2018 charitable deduction is attributable to product donations as compared to cash donations. Consistent with IRS requirements, Sanofi determines the amount of the charitable tax deduction for donations to foundations by calculating the lower of: (i) two times the cost of the drug (where cost is measured based on an adjusted WAC that subtracts certain discounts and fees); or (ii) cost plus half the product margin. This calculation is performed on a product-by-product basis.

Because Sanofi's 2018 tax return is not due until October 2019, Sanofi's 2018 deductible product donation amounts have not yet been finalized. At this point, and subject to change prior to filing, Sanofi estimates that product donations will result in a 2018 tax deduction of between \$23 and \$32 million.

**The Honorable Nanette Díaz Barragán (D-CA)**

- 1. Sanofi has filed 74 patent applications on Lantus, and more than 90 percent of these were filed after the drug was already approved and on the market. I'm concerned that these patents are not related to innovative improvements to the drug, but are part of Sanofi's strategy to further delay competition and retain control of this market.**

**Please explain the innovative nature of these patents filed after the approval of Lantus, and why they merit additional exclusivity to the detriment of diabetes patients?**

There are currently twenty-one patents listed in the FDA Orange Book for Lantus and Lantus SoloSTAR. Each patent granted on a Sanofi product, including the patents for Lantus and Lantus SoloSTAR, represents the US Patent and Trademark Office's (PTO) determination that the particular product innovation is worthy of patent protection. The PTO grants a patent only after conducting a lengthy examination process that tests whether the new invention meets all of the legal requirements for patentability, including that the invention is new, not obvious, and useful. Although many of the patents listed in the Orange Book were granted after FDA initially approved Lantus in 2000, FDA approval of a medicine does not foreclose future innovation with respect to that product. To the contrary, the PTO's patent process encourages ongoing innovation that further helps patients long after products are FDA-approved. Additionally, we note that patents granted after FDA approval do not limit competition in general, and have not limited competition in the diabetes market in particular. With respect to insulin, for example,

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Lantus faces competition from a follow-on biologic insulin glargine that launched shortly after the loss of patent exclusivity for the Lantus compound, despite the twenty-one patents currently listed.

By way of background, the patents granted for Lantus reflect that Sanofi's initial discovery of insulin glargine and subsequent development of an improved insulin glargine formulation and a more convenient, easy-to-use injection pen to deliver the insulin glargine have enhanced the lives of millions of patients living with diabetes in the United States and worldwide. The earliest insulin preparations were limited by their short duration of action, requiring patients to inject themselves multiple times a day and to wake up at night for injections in order to control blood glucose levels. Each such injection of insulin caused a sharp spike in the patient's insulin levels, which could cause symptoms of low blood sugar ranging from shakiness and confusion to, in the extreme, coma, or death. Injections also had to be timed before every meal, disrupting patient's lives, sleep times, and ability to eat with friends and family. As such, the consistent goals of insulin therapy have included reducing the frequency of insulin administration and flattening the post-administration peak of insulin in the bloodstream. Prior attempts to achieve these goals included cumbersome mechanical pumps that had to be worn on the body for constant infusion, and NPH insulin, which had an intermediate duration of action but still caused a pronounced peak in insulin levels.

The initial discovery and development of insulin glargine were therefore significant. Sanofi scientists succeeded in fundamentally altering the human insulin molecule at the amino acid level, changing its pharmacological characteristics to give patients a steady release of insulin with just a single daily administration. Unlike anything that came before it, glargine forms tiny solid crystals upon injection that dissipate over time to provide a flatter, stable, long-lasting effect that mimics the flat profile of insulin release from a healthy pancreas and reduces the risks caused by low blood sugar. The FDA approved insulin glargine under the tradename Lantus in 2000. But there was more to do to enhance the lives of patients with diabetes.

Lantus initially received FDA approval for, and launched, a vial; patients were required to inject the product with a syringe. Since that time, Sanofi has developed, received FDA approval for, and launched, several improved injection devices for administering glargine. Sanofi also reformulated the original Lantus vial formulation to solve the unexpected and unknown problem of potential cloudiness in prior Lantus vials and to make it more stable. The PTO awarded Sanofi two patents on this new formulation, both of which are listed in the Orange Book. Sanofi began selling its reformulated Lantus vial product in the U.S. in 2006, after the initial approval of Lantus.

Sanofi's latest pen delivery system, SoloSTAR, similarly has been a key improvement in easing the daily burden of insulin administration for patients. Sanofi partnered with premier design firms to develop this pre-filled, disposable injection pen for self-administration, which in turn has improved the lifestyle and medication compliance of diabetes patients. The SoloSTAR contains numerous features specifically designed to address the needs of people with diabetes, who often have health complications such as impaired vision and reduced dexterity. The pen's

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features include a clutch that can reversibly lock the complex device components in rotation to allow patients to “dial up” a dose for injection; dose dial stops that prevent patients from setting an excessive dose; a rotating dial that can easily correct an over-dialed dose; and a specially designed injection button that is easy for people with diabetes to depress and receive a highly accurate delivery of the set dose. All of the pen’s complex mechanical features and parts were seamlessly incorporated into the SoloSTAR’s design, while still providing a robust and reliable feel suitable for daily use by patients with a chronic condition. Sanofi launched the Lantus SoloSTAR in 2007. It has subsequently won awards for its novel design. The patents currently listed in the Orange Book for Lantus SoloSTAR relate to the SoloSTAR pen injector dosage form.

The PTO granted Sanofi patents for each of these innovations, reflecting that each met the PTO’s rigorous standards for patentability. Those patents protected Sanofi’s innovations; they have not served to inhibit competition.

**The Honorable Brett Guthrie (R-KY)**

1. **There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer decides to lower the list price of the medicine. Has Sanofi received a letter from any PBMs or insurers requesting that it provide the PBM or insurer with notice before Sanofi lowers the list price of insulin or any other medicine? If so, please list the entities that have sent such a letter to Sanofi and describe the requirements set forth in the letter.**

On December 14, 2018, Sanofi received a draft amendment to its Medicare Part D rebate agreement with OptumRx, Inc. (Optum). In the communication from Optum, Optum reported that a similar amendment would be forthcoming for the Sanofi-Optum commercial rebate agreement. The draft amendment requested that Sanofi provide advance written notice to Optum by March 1 of each calendar year if the following were to occur in that calendar year: 1) reduction of the WAC of any existing NDC; or 2) introduction or authorization of a lower priced authorized generic or a lower priced brand version of an existing NDC. Under the terms of the amendment, if Sanofi were to fail to notify Optum of a price reduction or launch of a lower list price alternative with the required advance notice, Optum would earn an “Effective Rebate Amount per Unit,” calculated as a dollar amount, per unit, based on the original WAC, for a set period of time. Sanofi has not signed the proposed amendment.

- a. **Does Sanofi have any contractual obligations to provide a supply chain partner with notice before lowering the list price of insulin or any other medicine? If so, please list the entities and describe the contractual provisions.**

With respect to insulins and most other Sanofi products, Sanofi is not party to any contractual requirements to provide supply chain partners, including health plans, PBMs, and wholesalers, with notice before lowering list price. Sanofi is currently party to contractual relationships with

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specialty distributors for certain rare disease products that require advance notification of price changes.

**b. Has Sanofi provided any of its supply chain partners with notice of a list price decrease? If so, please describe these interactions.**

No, Sanofi has not provided any of its supply chain partners with notice of a list price decrease.

**c. What happens to Sanofi's rebate obligations with PBMs if Sanofi lowers the list price of insulin or any other medicine?**

Because PBM rebates are currently set as a percentage of a product's list price, absent agreement to the contrary with the PBM, a lower list price would result in lower aggregate rebates per unit to the PBM. As noted above, one PBM has asked for advance written notice of such list price reductions. Other PBMs are currently evaluating and proposing various options to address the issue of lower list prices.

**d. Has the letter sent by OptumRx or any other similar requests by supply chain partners impacted Sanofi's decisions regarding whether to lower the list price of insulin or any other medicine? If so, please describe.**

Sanofi makes pricing changes based on its own independent assessment of the value proposition of the product, the competitive environment, patient access considerations, and investment in further product development or needs to reinvest in R&D more generally. Nevertheless, certain decisions by PBMs and wholesalers may affect a patient's ability to access Sanofi medicines. Because patient access considerations play a role in Sanofi's pricing decisions, actions by PBMs and wholesalers could have a future effect on those decisions.

**2. In Sanofi's testimony, Sanofi notes that the average net price of Sanofi's most prescribed insulin, Lantus, has declined by over 30 percent since 2012 while the average out-of-pocket burden for patients with commercial insurance and Medicare has increased by approximately 60 percent over that same period. Which factor described in Sanofi's testimony (e.g., list price, increase in number of high deductible health plans, changes in insurance design, changes to drug formularies, etc.) has had the greatest impact on the out-of-pocket burden for patients using insulin?**

The formulary design for health plans and PBMs is determined independently by the health plan or its PBM. Sanofi does not have visibility into that decision-making process and therefore believes that this question is best addressed to the health plans, or PBMs that represent or negotiate on behalf of health plans. However, we can confirm that Sanofi offers significant rebates on certain of our products in a highly competitive marketplace, including for Lantus. These negotiations have resulted in net prices that are well below the product's list price. While we do not have insight into PBM relationships with their clients, or their clients' relationships with pharmacies and patients, we do know that Lantus' average net price since 2012 has declined by more than 30% while the average out-of-pocket burden for commercially insured and Medicare patients has increased by approximately 60% over the same time period.

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- 3. According to a November 2018 I-MAK report on Lantus, 74 patent applications have been filed on Lantus and 95 percent of the patent applications on Lantus were filed after the drug was first approved and on the market in 2000.<sup>15</sup> Is this correct, and if so, why did Sanofi file these patent applications after the drug was first approved and on the market?**

Sanofi does not know the basis for the statement in the I-MAK report and is therefore unable to confirm the information in it. That said, there are currently twenty-one patents listed in the FDA Orange Book for Lantus or Lantus SoloSTAR. The patents currently listed in the Orange Book for Lantus SoloSTAR relate to the SoloSTAR pen injector dosage form. Those patents, granted by the PTO, protect Sanofi's innovations. Sanofi files patent applications when it believes that there has been meaningful innovation worthy of patent protection, but it is the PTO that ultimately decides when it is appropriate to grant a patent, based on its assessment of patentability. Innovation does not cease simply because a product has been approved by FDA. As described above, FDA's approval of Lantus did not halt innovation on Lantus or curtail competition. Sanofi filed new patent applications after Lantus's initial approval to protect new innovations with regard to the Lantus formulation as well as with the SoloSTAR pen device.

- a. How many of the patents relating to Lantus are on the insulin drug substance and how many are on the delivery device?**

Of the twenty-one patents listed in the FDA Orange Book for Lantus or Lantus SoloSTAR, nineteen relate to the Lantus SoloSTAR injectable pen product and two relate to the Lantus vial product. The insulin glargine compound patents previously listed in the Orange Book for Lantus and SoloSTAR expired in 2009 and late 2014 and thus are no longer listed in the Orange Book. We note that, in addition to the patents, the FDA grants regulatory exclusivity to new molecular entities that meet statutory standards. Those exclusivities for Lantus did not expire until February 2015.

- b. How many potentially competing products for Lantus has Sanofi challenged because of the existing patents on Lantus?**

Sanofi has initiated five patent infringement lawsuits against competitors to protect its innovations relating to Lantus.

In two lawsuits against Eli Lilly (one relating to the company's application to market and sell a vial product and another relating to its application for a pen product), Sanofi asserted infringement of certain formulation and device patents that were listed in the FDA Orange Book for Lantus or Lantus SoloSTAR. Eli Lilly and Sanofi entered into a settlement agreement to resolve one of the lawsuits in September 2015. Under the settlement, Eli Lilly was permitted to market Basaglar, a follow-on biologic to Lantus SoloSTAR, in December 2016, more than seven years before the last expiration date of the patents asserted in the Eli Lilly lawsuit. Basaglar is

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<sup>15</sup> I-MAK, Overpatented, Overpriced: Lantus (Nov. 1, 2018), available at <https://www.i-mak.org/lantus/>.

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currently on the market and competing against Lantus. The court dismissed the other lawsuit against Eli Lilly after the company decided against commercializing the product at issue.

In a September 2016 lawsuit against Merck following Merck's application for a follow-on biologic for Lantus and Lantus SoloSTAR, Sanofi asserted infringement of several drug and device patents listed in the FDA Orange Book for Lantus and Lantus SoloSTAR. Sanofi also filed a separate lawsuit against Merck in August 2017 alleging infringement of two other Orange Book-listed patents. Those lawsuits were both dismissed voluntarily at Merck's request, as Merck unilaterally decided not to commercialize follow-on versions of Lantus or Lantus SoloSTAR.

A lawsuit against Mylan and its development partner Biocon is ongoing, and involves claims that Mylan and Biocon have infringed certain formulation and device patents that are listed in the FDA Orange Book for Lantus or Lantus SoloSTAR.

**c. What impact, if any, did these patent applications have on the launch of Basaglar?**

Patent applications do not affect competition. Thus, Sanofi's patent applications have not impeded the launch of Basaglar, which occurred in 2016 -- more than seven years before the last expiration date of the patents asserted in the Eli Lilly lawsuit and not long after the expiration of the Lantus compound patent. Basaglar is currently on the market and competing against Lantus.

**4. Eli Lilly launched a follow-on insulin product—Basaglar—in 2016 to compete with Lantus. What impact, if any, has the launch of Basaglar had on the list price and net price of Lantus?**

The competition between Lantus and Basaglar has led to Sanofi substantially lowering the Lantus net price, as compared to prior years. Sanofi hopes that those price reductions will benefit patients but, as explained in our testimony and in the below chart, that does not appear to have been the case to date. As with all other Sanofi pricing decisions, any increase in the list price for Lantus since the launch of Basaglar has been consistent with Sanofi's progressive pricing policy, which includes a commitment to keep annual list price increases at or below the projected U.S. National Health Expenditure growth rate.

**5. We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. For example, in Sanofi's testimony, Sanofi said that, between 2012 and 2018, the average aggregate net price across all Sanofi insulin products has declined by 25 percent while the list price has increased by 126 percent. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many PBMs that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why**

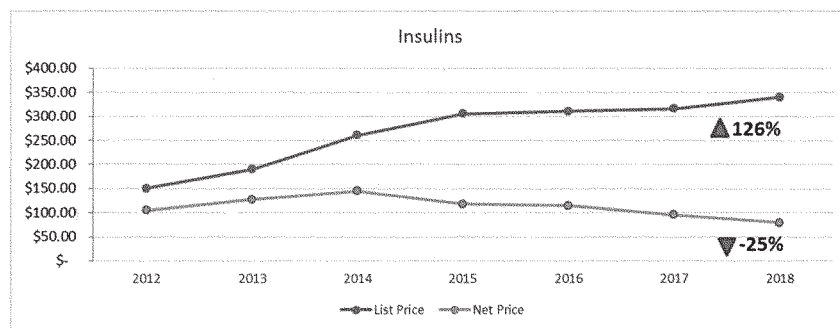
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**manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price. Please explain.**

As shown in the below chart, between 2012 and 2018, the average aggregate net price across all Sanofi insulin products has declined by 25 percent while the list price across all Sanofi insulin products has increased by 126 percent.

**Sanofi Insulins List vs. Net Price Changes Between 2012-2018**



In May 2017, Sanofi announced its progressive and industry-leading pricing principles to help stakeholders understand our pricing decisions and to advance a more informed discussion of issues related to the pricing of medicines.<sup>16</sup> These principles include a pledge to keep annual list price increases at or below the projected U.S. National Health Expenditure (NHE) growth rate, an estimate of medical spending calculated by the Centers for Medicare and Medicaid Services (CMS) and often used as a measure of healthcare inflation. These principles apply to all of our prescription medicines if a price increase results in more than a \$15 annual increase in the price of the medication. In addition, we committed to making both our average aggregate list and net price changes across our portfolio transparent to help illustrate how revenue accrues to Sanofi versus other parts of the pharmaceutical supply chain. In 2018, all of our price increases were consistent with our policy, as are all pricing actions we have taken in 2019.

With respect to PBMs interests, as HHS and HHS OIG have observed in their recent proposed Medicare Part D rebate rule, rebate payments and other forms of payment to PBMs are often based on a percentage of list price. Whether this causes PBMs to favor higher list price products over lower cost products is a question best directed to them, but it is clear that payments based on a percentage of list price result in a higher margin for the higher list price product than for the lower list price product. To illustrate this point, consider Sanofi's experience with Admelog, a biosimilar of insulin lispro. When it launched in 2017, Admelog was the lowest list price

<sup>16</sup> See [https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Prescription\\_Medicine\\_Pricing\\_2019.pdf](https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Prescription_Medicine_Pricing_2019.pdf).

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mealtime insulin product, yet it was not, and still is not, covered by any Medicare Part D or commercial plans. At the committee hearing, PBM witnesses testified that this was due to another product having a lower net price and a higher list price.<sup>17</sup> As we have experienced, within the current system, declining prices for payers or new treatments priced at responsibly lower list prices are no guarantee that those actions will translate to affordability or access for patients.

**6. During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are oftentimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.**

**a. What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?**

The payment of administrative fees that are a percentage of product list prices is a standard industry practice. The Anti-Kickback Statute safe harbor for GPO administrative fees protects percentage of list price-based administrative fees up to 3% of list price, and further protects percentage of list price-based fees above 3% if the fee amount is disclosed to the members of the GPO. In 2003, the OIG extended this safe harbor to PBM administrative fees.<sup>18</sup> Nevertheless, because percentage of list price payments could potentially create incentives for manufacturers to maintain high list prices, Sanofi supports reform of the current system to ensure that administrative fees are fixed and reflect fair market value for bona fide services performed for Sanofi.<sup>19</sup>

**b. Does your company support moving to a system where administrative fees are based on a flat fee instead?**

Yes, Sanofi supports a shift toward flat fees throughout the supply chain. Specifically, Sanofi supports the recent HHS OIG Proposed Rulemaking regarding the creation of a new safe harbor for PBM fees, and Sanofi has submitted comments on those proposals.

**The Honorable Jeff Duncan (R-SC)**

- 1. One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate**

<sup>17</sup> Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. on Oversight and Investigations, 116 Cong. 51 (2019) (Statement of Amy Bricker, Senior Vice President, Supply Chain, Express Scripts).

<sup>18</sup> Notice, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23736 (May 5, 2003).

<sup>19</sup> *Id.*

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**and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.**

**Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."**

**So, which is it? Is there innovation in the insulin market or not?**

There is substantial innovation in the diabetes marketplace, including for insulin products. Diabetes continues to be a critical area of focus of Sanofi's research and development efforts. Since Sanofi's discovery and development of Lantus, Sanofi has continued to invent new formulations to meet individualized patient needs. For example, Toujeo, approved by the FDA in 2015, more closely mimics endogenous basal insulin secretion and provides an improved therapeutic effect at a higher concentration of glargine than Lantus; Toujeo exhibits a different and longer-acting profile. In 2017, Sanofi launched Soliqua 100/33, a fixed-ratio combination of Lantus and a non-insulin glucagon-like peptide receptor agonist (GLP-1 RA) that starts working after eating a meal. GLP-1s have been shown to reduce post-mealtime glucose peaks, which have been linked to cardiovascular disease in patients with diabetes; however, their use has been limited by gastrointestinal side effects. Soliqua 100/33 has demonstrated reduction in average and overall glucose levels while also reducing the gastrointestinal side effects related to GLP-1s.

There has also been significant innovation related to insulin delivery mechanisms. As noted above, the launch of Lantus SoloSTAR has enhanced the lifestyles and medication compliance rates of millions of diabetes patients throughout the US and around the world. Sanofi has also developed Toujeo SoloSTAR, a pre-filled disposable injection pen that includes innovative design features and attributes, ranging from the length of time it can be held without overheating the contents to other ergonomic features designed to make the device easier to use.

Sanofi's scientists are working every day on ways to transform the future of diabetes care by addressing the underlying disease. Sanofi has initiated multi-pronged research efforts aimed at preventing progression of the disease, reducing insulin-dependence, and restoring insulin-producing cells through stem cell technologies. Sanofi researchers are also exploring the molecular mechanisms by which obesity leads to diabetes, and they are working to design molecules that aim to restore healthy metabolism and thereby stop diabetes in its tracks. Sanofi is committed to continued investment so that we can bring better and more convenient breakthrough treatments to diabetes patients.

2. **One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."**

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**Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."**

**So, which is it? Are there patents preventing innovation and competition or not?**

Patents are not preventing innovation and competition. To the contrary, there is robust competition among diabetes drug manufacturers. This competition only continues to intensify with the introduction of additional generic and biosimilar medicines. As with any technology, this a reflection of the number of problems that had to be solved with novel and innovative solutions to bring the technology to the market. Sanofi's patents reflect novel inventions, as evidenced by PTO's grant of those patents. US patents are granted only after a comprehensive examination process by the PTO that tests whether the invention meets all the legal requirements of patentability including that the invention be new, not obvious, and useful.

Sanofi invests billions of dollars in the pursuit of new treatments for patients and our patents serve to protect our innovative discoveries. From 2012 through 2018, Sanofi's total research and development (R&D) investment in diabetes was approximately \$4.5 billion. In 2018 alone, Sanofi's total research and development investment in diabetes was approximately \$800 million. Sanofi plans to maintain this level of research and development investment through 2021. From a life sciences perspective, the patent system serves to attract the risk-taking, entrepreneurial spirit, and the capital needed to engage the brightest minds in science to solve some of the world's greatest health challenges—in short, the patent system encourages innovation.